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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L. AND MEDTRONIC VASCULAR GALWAY LTD.,

Plaintiffs,

v.

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES (U.S.) INC.,

Defendants.

Case SACV11-00961 JVS(MLGx)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., and Medtronic Vascular Galway, Ltd. (collectively "Medtronic") for their Complaint against Defendants Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc., hereby states and alleges as follows:

I.
INTRODUCTION

1. This is an action for willful infringement by Defendants of a United States patent owned by Medtronic CoreValve LLC.

2. Plaintiff Medtronic CoreValve LLC is a limited liability company organized and existing under the laws of Delaware, with its principal place of business in Irvine, California.

3. Plaintiff Medtronic CV Luxembourg S.a.r.l. is a limited liability company organized and existing under the laws of Luxembourg, with its principal place of business in Luxembourg.

4. Plaintiff Medtronic Vascular Galway Ltd. is a company organized and existing under the laws of Ireland, with its principal place of business in Galway, Ireland.

5. Upon information and belief, Defendant Lifesciences Corporation is a corporation organized and existing under the laws of Delaware with its principal place of business in Irvine, California.

6. Upon information and belief, Defendant Edward Lifesciences LLC is a wholly-owned subsidiary of Edwards Lifesciences Corporation that is organized under the laws of Delaware with its principal place of business in Irvine, California.

7. Upon information and belief, Defendant Edwards Lifesciences (U.S.) Inc. is a wholly-owned subsidiary of Edwards Lifesciences Corporation that is organized under the laws of Delaware with its principal place of business in Irvine, California. Edwards Lifesciences Corporation, Edwards Lifesciences LLC and

Edwards Lifesciences (U.S.) Inc. are collectively hereinafter referred to as "Edwards."

II.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and § 1338(a) in that this action arises under the patent laws of the United States.

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

10. This Court has personal jurisdiction over the Defendants because, upon information and belief, Defendants conduct business within this judicial district, and have their principal places of business within this judicial district. Upon information and belief, Defendants have committed and continue to commit acts of patent infringement within this judicial district.

III.

FACTUAL BACKGROUND

11. Plaintiff Medtronic CoreValve LLC is the lawful owner of United States Patent No. 7,892,281 ("the '281 Patent"), which was duly and legally issued by the United States Patent and Trademark Office on February 22, 2011. The '281 Patent is entitled "Prosthetic Valve for Transluminal Delivery." A copy of the '281 Patent is attached hereto as Exhibit 1.

12. Plaintiff Medtronic CV Luxembourg S.a.r.l. is the exclusive licensee of the '281 Patent.

13. Plaintiff Medtronic Vascular Galway Ltd. holds world wide manufacturing and distribution rights to the '281 Patent.

14. Collectively, the Medtronic Plaintiffs own all rights, title and interests in the '281 Patent.

15. Medtronic has the exclusive right under the patent laws of the United States to exclude others from making, using, offering for sale, selling, or importing its patented invention, including the right to bring this action for injunctive relief, and accounting and damages.

IV.

COUNT I

(Claim for Patent Infringement of U.S. Patent No. 7,892,281)

16. Medtronic hereby restates and re-alleges the allegations set forth in Paragraphs 1 through 15 and incorporates them into this count by reference.

17. Upon information and belief Defendant Edwards manufactures in the Central District of California and elsewhere within the United States devices that infringe, either literally or under the Doctrine of Equivalents, one or more claims of the '281 Patent. Such devices include, but are not limited to, the Sapien Transcatheter Aortic Valve.

18. Upon information and belief, and in violation of 35 U.S.C. § 271, Edwards has been and is now infringing the '281 patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve devices covered by one or more claims of the '281 patent, including without limitation the Sapien Transcatheter Aortic Valve.

19. Edwards' foregoing infringement has been willful, warranting a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285.

20. The unlawful infringing activities by Defendant Edwards are continuing and will continue unless enjoined by this Court.

21. As a result of the infringing acts herein described, Medtronic has sustained damages and will continue to sustain damages in the future, including irreparable harm, unless Defendant Edwards is enjoined from infringing said patent.

V.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Medtronic prays for judgment against Defendants as follows:

1. That Defendants have infringed, either literally or under the Doctrine of Equivalents, one or more claims of the '281 Patent;

2. That Defendants' infringement has been willful and trebling the award of damages;

3. That Defendants, and their respective agents, servants, officers, directors, employees and all persons acting in concert with them, directly or indirectly, be permanently enjoined from infringing the '281 Patent;

4. That Defendants account for and pay to Plaintiff damages adequate to compensate them for Defendants' infringement, in an amount to be proven at trial, together with interest and costs as fixed by the Court;

5. Declaring that this case is exceptional and awarding Plaintiff its costs and attorneys' fees in accordance with 35 U.S.C. § 285; and

6. That Plaintiff be awarded such other and further relief as the Court may deem just and equitable.

Dated: June 24, 2011

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

By: _____
David Martinez
Jan Conlin
Stacie Oberts
Lauren Wood

Attorneys for Plaintiffs MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., and MEDTRONIC VASCULAR GALWAY LTD.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all matters so triable.

Dated: June 24, 2011

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

By: David M / ATTNEY
David Martinez
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Lauren Wood

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EXHIBIT 1

US007892281B2

(12) **United States Patent**
Seguin et al.

(10) **Patent No.: US 7,892,281 B2**
(45) **Date of Patent: *Feb. 22, 2011**

(54) **PROSTHETIC VALVE FOR TRANSLUMINAL DELIVERY**

(75) Inventors: **Jacques Seguin**, Old Windsor (GB); **Georg Börtlein**, Meudon (FR)

(73) Assignee: **Medtronic CoreValve LLC**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/348,892**

(22) Filed: **Jan. 5, 2009**

(65) **Prior Publication Data**

US 2009/0164006 A1 Jun. 25, 2009

Related U.S. Application Data

(63) Continuation of application No. 12/029,031, filed on Feb. 11, 2008, which is a continuation of application No. 11/352,614, filed on Feb. 13, 2006, now Pat. No. 7,329,278, which is a continuation of application No. 10/412,634, filed on Apr. 10, 2003, now Pat. No. 7,018,406, which is a continuation-in-part of application No. 10/130,355, filed as application No. PCT/FR00/03176 on Nov. 15, 2000, now Pat. No. 6,830,584, and a continuation-in-part of application No. PCT/FR01/03258, filed on Oct. 19, 2001, application No. 12/348,892, which is a continuation of application No. 11/434,506, filed on May 15, 2006, which is a continuation-in-part of application No. 10/772,101, filed on Feb. 4, 2004, which is a continuation-in-part of application No. 10/412,634.

(30) **Foreign Application Priority Data**

Nov. 17, 1999 (FR) 99/14462
Nov. 17, 1999 (FR) 99/14462

(51) **Int. Cl.**
A61F 2/24 (2006.01)

(52) **U.S. Cl.** **623/2.1**

(58) **Field of Classification Search** 623/2.1–2.24
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,832,078 A * 4/1958 Williams 623/2.19

(Continued)

FOREIGN PATENT DOCUMENTS

DE 195 32 846 3/1997

(Continued)

OTHER PUBLICATIONS

U.S. Appl. No. 12/250,163, filed Oct. 13, 2008.

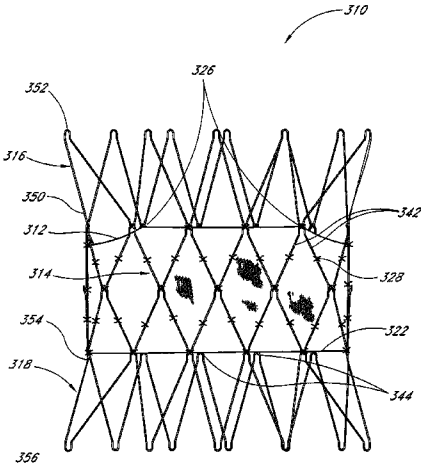
(Continued)

Primary Examiner—Suzette J Gherbi
(74) *Attorney, Agent, or Firm*—Jeffrey J. Hohenshell; Mike Jaro

(57) **ABSTRACT**

A prosthetic valve assembly for use in replacing a deficient native valve comprises a replacement valve supported on an expandable valve support. If desired, one or more anchor may be used. The valve support, which entirely supports the valve annulus, valve leaflets, and valve commissure points, is configured to be collapsible for transluminal delivery and expandable to contact the anatomical annulus of the native valve when the assembly is properly positioned. The anchor engages the lumen wall when expanded and prevents substantial migration of the valve assembly when positioned in place. The prosthetic valve assembly is compressible about a catheter, and restrained from expanding by an outer sheath. The catheter may be inserted inside a lumen within the body, such as the femoral artery, and delivered to a desired location, such as the heart. When the outer sheath is retracted, the prosthetic valve assembly expands to an expanded position such that the valve and valve support expand within the deficient native valve, and the anchor engages the lumen wall.

15 Claims, 25 Drawing Sheets



U.S. PATENT DOCUMENTS

3,334,629 A 8/1967 Cohn
3,409,013 A 11/1968 Berry
3,540,431 A 11/1970 Mobin-Uddin
3,587,115 A 6/1971 Shiley
3,628,535 A 12/1971 Ostrowsky et al
3,642,004 A 2/1972 Osthagen et al
3,657,744 A * 4/1972 Ersek 128/898
3,671,979 A 6/1972 Moulopoulos
3,714,671 A 2/1973 Edwards et al.
3,755,823 A 9/1973 Hancock
3,795,246 A 3/1974 Sturgeon
3,839,741 A 10/1974 Haller
3,868,956 A 3/1975 Alfidi et al
3,874,388 A 4/1975 King et al
4,035,849 A 7/1977 Angell et al.
4,056,854 A 11/1977 Boretos et al.
4,106,129 A 8/1978 Carpentier et al.
4,222,126 A 9/1980 Boretos et al.
4,233,690 A 11/1980 Akins
4,265,694 A 5/1981 Boretos
4,291,420 A 9/1981 Reul
4,297,749 A 11/1981 Davis et al.
4,339,831 A 7/1982 Johnson
4,343,048 A 8/1982 Ross et al.
4,345,340 A 8/1982 Rosen
4,425,908 A 1/1984 Simon
4,470,157 A 9/1984 Love
4,501,030 A 2/1985 Lane
4,574,803 A 3/1986 Storz
4,580,568 A 4/1986 Gianturco
4,592,340 A 6/1986 Boyles
4,610,688 A 9/1986 Silvestrini et al.
4,612,011 A 9/1986 Kautzky
4,647,283 A 3/1987 Carpentier et al.
4,648,881 A 3/1987 Carpentier et al.
4,655,771 A 4/1987 Wallsten
4,662,885 A 5/1987 DiPisa, Jr.
4,665,906 A 5/1987 Jervis
4,681,908 A 7/1987 Broderick et al.
4,710,192 A 12/1987 Liotta et al.
4,733,665 A 3/1988 Palmaz
4,777,951 A 10/1988 Cribier et al.
4,787,899 A 11/1988 Lazarus
4,796,629 A 1/1989 Grayzel
4,797,901 A 1/1989 Baykut
4,819,751 A 4/1989 Shimada et al.
4,834,755 A 5/1989 Silvestrini et al.
4,851,000 A * 7/1989 Gupta 623/2.18
4,856,516 A 8/1989 Hillstead
4,872,874 A 10/1989 Taheri
4,878,495 A 11/1989 Grayzel
4,878,906 A 11/1989 Lindemann et al.
4,883,458 A 11/1989 Shiber
4,909,252 A 3/1990 Goldberger
4,917,102 A 4/1990 Miller et al.
4,922,905 A 5/1990 Strecker
4,954,126 A 9/1990 Wallsten
4,966,604 A 10/1990 Reiss
4,979,939 A 12/1990 Shiber
4,986,830 A 1/1991 Owens et al.
4,994,077 A 2/1991 Dobben
5,002,559 A 3/1991 Tower
5,007,896 A 4/1991 Shiber
5,026,366 A 6/1991 Leckrone
5,032,128 A 7/1991 Alonso
5,037,434 A 8/1991 Lane
5,047,041 A 9/1991 Samuels
5,059,177 A 10/1991 Towne et al.
5,061,273 A 10/1991 Yock
5,085,635 A 2/1992 Cragg
5,089,015 A 2/1992 Ross
5,152,771 A 10/1992 Sabbaghian et al.
5,161,547 A 11/1992 Tower
5,163,953 A 11/1992 Vince
5,167,628 A 12/1992 Boyles
5,217,483 A 6/1993 Tower
5,232,445 A 8/1993 Bonzel
5,272,909 A 12/1993 Nguyen et al.
5,295,958 A 3/1994 Shturman
5,327,774 A 7/1994 Nguyen et al.
5,332,402 A 7/1994 Teitelbaum et al.
5,350,398 A 9/1994 Pavcnik et al.
5,370,685 A 12/1994 Stevens
5,389,106 A 2/1995 Tower
5,397,351 A 3/1995 Pavcnik et al.
5,411,552 A 5/1995 Andersen et al.
5,415,633 A 5/1995 Lazarus et al.
5,431,676 A 7/1995 Dubrul et al.
5,443,446 A 8/1995 Shturman
5,480,424 A 1/1996 Cox
5,489,294 A 2/1996 McVenes et al.
5,489,297 A 2/1996 Duran
5,496,346 A 3/1996 Horzewski et al.
5,500,014 A 3/1996 Quijano et al.
5,507,767 A 4/1996 Maeda et al.
5,545,209 A 8/1996 Roberts et al.
5,545,211 A 8/1996 An et al.
5,545,214 A 8/1996 Stevens
5,554,185 A 9/1996 Block et al.
5,575,818 A 11/1996 Pinchuk
5,580,922 A 12/1996 Park et al.
5,591,195 A 1/1997 Taheri et al.
5,609,626 A 3/1997 Quijano et al.
5,645,559 A 7/1997 Hachtman et al.
5,665,115 A 9/1997 Cragg
5,667,523 A 9/1997 Bynon et al.
5,674,277 A 10/1997 Freitag
5,695,498 A 12/1997 Tower
5,702,368 A 12/1997 Stevens et al.
5,713,953 A 2/1998 Vallana et al.
5,716,417 A * 2/1998 Girard et al. 623/2.38
5,746,709 A 5/1998 Rom et al.
5,749,890 A 5/1998 Shaknovich
5,766,151 A 6/1998 Valley et al.
5,782,809 A 7/1998 Umeno et al.
5,800,456 A 9/1998 Maeda et al.
5,800,508 A 9/1998 Goicoechea et al.
5,817,126 A 10/1998 Imran
5,824,041 A 10/1998 Lenker
5,824,043 A 10/1998 Cottone, Jr.
5,824,053 A 10/1998 Khosravi et al.
5,824,056 A 10/1998 Rosenberg
5,824,061 A 10/1998 Quijano et al.
5,824,064 A 10/1998 Taheri
5,840,081 A 11/1998 Andersen et al.
5,843,158 A 12/1998 Lenker et al.
5,851,232 A 12/1998 Lois
5,855,597 A 1/1999 Jayaraman
5,855,601 A 1/1999 Bessler et al.
5,860,996 A 1/1999 Tower
5,861,028 A 1/1999 Angell
5,868,783 A 2/1999 Tower
5,876,448 A 3/1999 Thompson et al.
5,888,201 A 3/1999 Stinson et al.
5,891,191 A 4/1999 Stinson
5,906,619 A 5/1999 Olson et al.
5,907,893 A 6/1999 Zadno-Azizi et al.
5,913,842 A 6/1999 Boyd et al.
5,925,063 A 7/1999 Khosravi
5,944,738 A 8/1999 Amplatz et al.
5,951,288 A * 9/1999 Sawa 433/173
5,954,766 A 9/1999 Zadno-Azizi et al.
5,957,949 A * 9/1999 Leonhardt et al. 623/1.24
5,968,068 A 10/1999 Dehdashtian et al.

5,984,957	A	11/1999	Laptewicz, Jr. et al.	6,663,663	B2	12/2003	Kim et al.
5,997,573	A	12/1999	Quijano et al.	6,669,724	B2	12/2003	Park et al.
6,022,370	A	2/2000	Tower	6,673,089	B1	1/2004	Yassour et al.
6,027,525	A	2/2000	Suh et al.	6,673,109	B2	1/2004	Cox
6,029,671	A	2/2000	Stevens et al.	6,676,698	B2	1/2004	McGuckin, Jr. et al.
6,042,589	A	3/2000	Marianne	6,682,558	B2	1/2004	Tu et al.
6,042,598	A	3/2000	Tsugita et al.	6,682,559	B2	1/2004	Myers et al.
6,042,607	A	3/2000	Williamson, IV	6,685,739	B2	2/2004	DiMatteo et al.
6,051,014	A	4/2000	Jang	6,689,144	B2	2/2004	Gerberding
6,059,809	A	5/2000	Amor et al.	6,689,164	B1	2/2004	Seguin
6,110,201	A	8/2000	Quijano et al.	6,692,512	B2	2/2004	Jang
6,146,366	A	11/2000	Schachar	6,692,513	B2	2/2004	Streeter et al.
6,159,239	A	12/2000	Greenhalgh	6,695,878	B2	2/2004	McGuckin, Jr. et al.
6,162,208	A	12/2000	Hipps	6,702,851	B1	3/2004	Chinn et al.
6,162,245	A	12/2000	Jayaraman	6,719,789	B2	4/2004	Cox
6,168,614	B1	1/2001	Andersen et al.	6,730,118	B2	5/2004	Spenser et al.
6,171,335	B1	1/2001	Wheatley et al.	6,730,377	B2	5/2004	Wang
6,200,336	B1	3/2001	Pavcnik et al.	6,371,970	B1	4/2002	Khosravi et al.
6,203,550	B1	3/2001	Olson	6,733,525	B2	5/2004	Yang et al.
6,210,408	B1	4/2001	Chandrasekaran et al.	6,736,846	B2	5/2004	Cox
6,218,662	B1	4/2001	Tchakarov et al.	6,752,828	B2	6/2004	Thornton
6,221,006	B1	4/2001	Dubrul et al.	6,758,855	B2	7/2004	Fulton, III et al.
6,221,091	B1	4/2001	Khosravi	6,769,434	B2	8/2004	Liddicoat et al.
6,241,757	B1	6/2001	An et al.	6,786,925	B1	9/2004	Schoon
6,245,102	B1	6/2001	Jayaraman	6,790,229	B1	9/2004	Berreklouw
6,248,116	B1	6/2001	Chevillon	6,792,979	B2	9/2004	Konya et al.
6,258,114	B1	7/2001	Konya et al.	6,797,002	B2	9/2004	Spence
6,258,115	B1	7/2001	Dubrul	6,821,297	B2	11/2004	Snyders
6,258,120	B1	7/2001	McKenzie et al.	6,830,575	B2	12/2004	Stenzel et al.
6,277,555	B1	8/2001	Duran et al.	6,830,584	B1	12/2004	Seguin
6,299,637	B1	10/2001	Shaolia et al.	6,830,585	B1	12/2004	Artof
6,302,906	B1	10/2001	Goicoechea et al.	6,846,325	B2	1/2005	Liddicoat
6,309,382	B1	10/2001	Garrison et al.	6,866,650	B2	3/2005	Stevens
6,309,417	B1	10/2001	Spence et al.	6,872,223	B2	3/2005	Roberts
6,327,772	B1	12/2001	Zadno-Azizi et al.	6,875,231	B2	4/2005	Anduiza et al.
6,338,735	B1	1/2002	Stevens	6,883,522	B2	4/2005	Spence et al.
6,348,063	B1	2/2002	Yassour et al.	6,887,266	B2	5/2005	Williams et al.
6,350,277	B1	2/2002	Kocur	6,890,330	B2	5/2005	Streeter et al.
6,352,708	B1	3/2002	Duran et al.	6,893,460	B2	5/2005	Spenser et al.
6,371,983	B1	4/2002	Lane	6,896,690	B1	5/2005	Lambrecht et al.
6,379,383	B1	4/2002	Palmaz et al.	6,908,481	B2	6/2005	Cribier
6,380,457	B1	4/2002	Yurek et al.	6,913,600	B2	7/2005	Valley et al.
6,398,807	B1	6/2002	Chouinard et al.	6,929,653	B2	8/2005	Streeter
6,409,750	B1	6/2002	Hyodoh et al.	6,936,066	B2	8/2005	Palmaz et al.
6,425,916	B1	7/2002	Garrison et al.	6,939,365	B1	9/2005	Fogarty et al.
6,440,164	B1	8/2002	DiMatteo et al.	6,951,571	B1	10/2005	Srivastava
6,454,799	B1	9/2002	Schreck	6,986,742	B2	1/2006	Hart et al.
6,458,153	B1	10/2002	Bailey et al.	6,989,027	B2	1/2006	Allen et al.
6,461,382	B1	10/2002	Cao	6,989,028	B2	1/2006	Lashinski et al.
6,468,303	B1	10/2002	Amplatz et al.	6,991,649	B2	1/2006	Sievers
6,475,239	B1	11/2002	Campbell et al.	7,018,401	B1	3/2006	Hyodoh et al.
6,482,228	B1	11/2002	Norred	7,018,406	B2 *	3/2006	Seguin et al. 623/2.1
6,488,704	B1	12/2002	Connelly et al.	7,041,128	B2	5/2006	McGuckin, Jr. et al.
6,494,909	B2	12/2002	Greenhalgh	7,044,966	B2	5/2006	Svanidze et al.
6,503,272	B2	1/2003	Duerig et al.	7,048,014	B2	5/2006	Hyodoh et al.
6,508,833	B2	1/2003	Pavcnik et al.	7,097,659	B2	8/2006	Woolfson et al.
6,527,800	B1	3/2003	McGuckin, Jr. et al.	7,101,396	B2	9/2006	Artof et al.
6,530,949	B2	3/2003	Konya et al.	7,105,016	B2	9/2006	Shui et al.
6,530,952	B2	3/2003	Vesely	7,115,141	B2	10/2006	Menz et al.
6,562,031	B2	5/2003	Chandrasekaran et al.	7,147,663	B1	12/2006	Berg et al.
6,562,058	B2	5/2003	Seguin et al.	7,153,324	B2	12/2006	Case et al.
6,569,191	B1 *	5/2003	Hogan 623/1.11	7,160,319	B2	1/2007	Chouinard et al.
6,569,196	B1	5/2003	Vesely	7,175,656	B2	2/2007	Khairkhahan
6,585,758	B1	7/2003	Chouinard et al.	7,186,265	B2	3/2007	Sharkawy et al.
6,592,546	B1	7/2003	Barbut et al.	7,195,641	B2	3/2007	Palmaz et al.
6,605,112	B1	8/2003	Moll et al.	7,198,646	B2	4/2007	Figulla et al.
6,613,077	B2	9/2003	Gilligan et al.	7,201,761	B2	4/2007	Woolfson et al.
6,622,604	B1	9/2003	Chouinard et al.	7,201,772	B2	4/2007	Schwammenthal et al.
6,632,243	B1	10/2003	Zadno-Azizi et al.	7,252,682	B2	8/2007	Seguin
6,635,068	B1	10/2003	Dubrul et al.	7,300,457	B2	11/2007	Palmaz
6,652,571	B1	11/2003	White et al.	7,300,463	B2	11/2007	Liddicoat
6,652,578	B2	11/2003	Bailey et al.	7,316,706	B2	1/2008	Bloom et al.
6,656,213	B2	12/2003	Solem	7,329,278	B2	2/2008	Seguin

7,335,218	B2	2/2008	Wilson et al.
7,338,520	B2	3/2008	Bailey et al.
7,374,571	B2	5/2008	Pease et al.
7,381,218	B2	6/2008	Shreck
7,384,411	B1	6/2008	Condado
7,429,269	B2	9/2008	Schwammenthal et al.
7,442,204	B2	10/2008	Schwammenthal et al.
7,462,191	B2	12/2008	Spenser et al.
7,470,284	B2	12/2008	Lambrecht et al.
7,481,838	B2	1/2009	Carpentier et al.
7,544,206	B2	6/2009	Cohn et al.
7,556,646	B2	7/2009	Yang et al.
7,682,390	B2	3/2010	Seguin
7,780,726	B2	8/2010	Seguin
7,806,919	B2	10/2010	Bloom et al.
2001/0001314	A1	5/2001	Davison et al.
2001/0002445	A1	5/2001	Vesely
2001/0007956	A1	7/2001	Letac et al.
2001/0010017	A1	7/2001	Letac et al.
2001/0011189	A1	8/2001	Drasler et al.
2001/0021872	A1	9/2001	Bailey et al.
2001/0025196	A1	9/2001	Chinn et al.
2001/0032013	A1	10/2001	Marton
2001/0039450	A1	11/2001	Pavcnik et al.
2001/0041928	A1	11/2001	Pavcnik et al.
2001/0044647	A1	11/2001	Pinchuk et al.
2002/0010508	A1	1/2002	Chobotov
2002/0029014	A1	3/2002	Jayaraman
2002/0032480	A1	3/2002	Spence et al.
2002/0032481	A1	3/2002	Gabbay
2002/0035396	A1	3/2002	Heath
2002/0042650	A1	4/2002	Vardi et al.
2002/0052651	A1	5/2002	Myers et al.
2002/0058995	A1	5/2002	Stevens
2002/0072789	A1	6/2002	Hackett et al.
2002/0077696	A1	6/2002	Zadno-Azizi et al.
2002/0095209	A1	7/2002	Zadno-Azizi et al.
2002/0099439	A1	7/2002	Schwartz et al.
2002/0103533	A1	8/2002	Langberg et al.
2002/0107565	A1	8/2002	Greenhalgh
2002/0111674	A1	8/2002	Chouinard et al.
2002/0123802	A1	9/2002	Snyders
2002/0133183	A1	9/2002	Lentz et al.
2002/0138138	A1	9/2002	Yang
2002/0151970	A1	10/2002	Garrison et al.
2002/0161392	A1	10/2002	Dubrul
2002/0161394	A1	10/2002	Macoviak et al.
2002/0193871	A1	12/2002	Beyersdorf et al.
2003/0014104	A1	1/2003	Cribier
2003/0023300	A1	1/2003	Bailey et al.
2003/0023303	A1	1/2003	Palmaz et al.
2003/0028247	A1	2/2003	Cali
2003/0036791	A1	2/2003	Bonhoeffer et al.
2003/0040771	A1	2/2003	Hyodoh et al.
2003/0040772	A1	2/2003	Hyodoh et al.
2003/0040792	A1	2/2003	Gabbay
2003/0050694	A1	3/2003	Yang et al.
2003/0055495	A1	3/2003	Pease et al.
2003/0065386	A1	4/2003	Weadock
2003/0069492	A1	4/2003	Abrams et al.
2003/0109924	A1	6/2003	Cribier
2003/0125795	A1	7/2003	Pavcnik et al.
2003/0130726	A1	7/2003	Thorpe et al.
2003/0130729	A1	7/2003	Paniagua et al.
2003/0139804	A1	7/2003	Hankh et al.
2003/0149475	A1	8/2003	Hyodoh et al.
2003/0149476	A1	8/2003	Damm et al.
2003/0149478	A1	8/2003	Figulla et al.
2003/0153974	A1	8/2003	Spenser et al.
2003/0181850	A1	9/2003	Diamond et al.
2003/0191519	A1	10/2003	Lombardi et al.
2003/0199913	A1	10/2003	Dubrul et al.
2003/0199963	A1	10/2003	Tower et al.
2003/0199971	A1	10/2003	Tower et al.
2003/0199972	A1	10/2003	Zadno-Azizi et al.
2003/0212410	A1	11/2003	Stenzel et al.
2003/0212452	A1	11/2003	Zadno-Azizi et al.
2003/0212454	A1	11/2003	Scott et al.
2004/0034411	A1	2/2004	Quijano et al.
2004/0039436	A1	2/2004	Spenser et al.
2004/0049224	A1	3/2004	Buehlmann et al.
2004/0049262	A1	3/2004	Obermiller et al.
2004/0049266	A1	3/2004	Anduiza et al.
2004/0082904	A1	4/2004	Houde et al.
2004/0088045	A1	5/2004	Cox
2004/0093005	A1	5/2004	Durcan
2004/0093060	A1	5/2004	Seguin et al.
2004/0097788	A1	5/2004	Mourlas et al.
2004/0098112	A1	5/2004	DiMatteo et al.
2004/0106976	A1	6/2004	Bailey et al.
2004/0106990	A1	6/2004	Spence et al.
2004/0111096	A1	6/2004	Tu et al.
2004/0116951	A1	6/2004	Rosengart
2004/0117004	A1	6/2004	Osborne et al.
2004/0122468	A1	6/2004	Yodfat et al.
2004/0122516	A1	6/2004	Fogarty
2004/0127979	A1	7/2004	Wilson
2004/0138742	A1	7/2004	Myers et al.
2004/0138743	A1	7/2004	Myers et al.
2004/0153146	A1	8/2004	Lashinski et al.
2004/0167573	A1	8/2004	Williamson
2004/0167620	A1	8/2004	Ortiz
2004/0186563	A1	9/2004	Iobbi
2004/0193261	A1	9/2004	Berreklouw
2004/0210240	A1	10/2004	Saint
2004/0210304	A1	10/2004	Seguin et al.
2004/0210307	A1	10/2004	Khairkhahan
2004/0215333	A1	10/2004	Duran
2004/0215339	A1	10/2004	Drasler et al.
2004/0225353	A1	11/2004	McGuckin, Jr.
2004/0225354	A1	11/2004	Allen
2004/0254636	A1	12/2004	Flagle et al.
2004/0260394	A1	12/2004	Douk et al.
2004/0267357	A1	12/2004	Allen et al.
2005/0010246	A1	1/2005	Streeter
2005/0010285	A1	1/2005	Lambrecht et al.
2005/0010287	A1	1/2005	Macoviak
2005/0015112	A1	1/2005	Cohn et al.
2005/0027348	A1	2/2005	Case et al.
2005/0033398	A1	2/2005	Seguin
2005/0043790	A1	2/2005	Seguin
2005/0049692	A1	3/2005	Numamoto
2005/0049696	A1	3/2005	Siess
2005/0055088	A1	3/2005	Liddicoat et al.
2005/0060029	A1	3/2005	Le
2005/0060030	A1	3/2005	Lashinski et al.
2005/0075584	A1	4/2005	Cali
2005/0075712	A1	4/2005	Biancucci
2005/0075717	A1	4/2005	Nguyen
2005/0075719	A1	4/2005	Bergheim
2005/0075724	A1	4/2005	Svanidze
2005/0075727	A1	4/2005	Wheatley
2005/0075730	A1	4/2005	Myers
2005/0075731	A1	4/2005	Artof
2005/0085841	A1	4/2005	Eversull et al.
2005/0085842	A1	4/2005	Eversull et al.
2005/0085843	A1	4/2005	Opolski et al.
2005/0085890	A1	4/2005	Rasmussen et al.
2005/0085900	A1	4/2005	Case et al.
2005/0096568	A1	5/2005	Kato
2005/0096692	A1	5/2005	Linder et al.
2005/0096724	A1	5/2005	Stenzel et al.
2005/0096734	A1	5/2005	Majercak et al.
2005/0096735	A1	5/2005	Hojeibane et al.
2005/0096736	A1	5/2005	Osse et al.
2005/0096738	A1	5/2005	Cali et al.

2005/0107871	A1	5/2005	Realyvasquez et al.
2005/0113910	A1	5/2005	Paniagua
2005/0119688	A1	6/2005	Berheim
2005/0131438	A1	6/2005	Cohn
2005/0137686	A1	6/2005	Salahieh
2005/0137688	A1	6/2005	Salahieh et al.
2005/0137692	A1	6/2005	Haug
2005/0137695	A1	6/2005	Salahieh
2005/0137701	A1	6/2005	Salahieh
2005/0143809	A1	6/2005	Salahieh
2005/0148997	A1	7/2005	Valley et al.
2005/0165477	A1	7/2005	Anduiza et al.
2005/0187616	A1	8/2005	Realyvasquez
2005/0203549	A1	9/2005	Realyvasquez
2005/0203605	A1	9/2005	Dolan
2005/0203618	A1	9/2005	Sharkawy
2005/0222674	A1	10/2005	Paine
2005/0228495	A1	10/2005	Macoviak
2005/0234546	A1	10/2005	Nugent
2005/0240200	A1	10/2005	Bergheim
2005/0240263	A1	10/2005	Fogarty et al.
2005/0261759	A1	11/2005	Lambrecht et al.
2005/0283962	A1	12/2005	Boudjemline
2006/0004439	A1	1/2006	Spenser et al.
2006/0009841	A1	1/2006	McGuckin et al.
2006/0052867	A1	3/2006	Revuelta et al.
2006/0058775	A1	3/2006	Stevens et al.
2006/0089711	A1	4/2006	Dolan
2006/0100685	A1	5/2006	Seguin et al.
2006/0116757	A1	6/2006	Lashinski et al.
2006/0135964	A1	6/2006	Vesely
2006/0142848	A1	6/2006	Gabbay
2006/0167474	A1	7/2006	Bloom et al.
2006/0178740	A1	8/2006	Stacchino et al.
2006/0195134	A1	8/2006	Crittenden
2006/0206192	A1	9/2006	Tower et al.
2006/0206202	A1	9/2006	Bonhoefer et al.
2006/0247763	A1	11/2006	Slater
2006/0259134	A1	11/2006	Schwammenthal et al.
2006/0259136	A1	11/2006	Nguyen et al.
2006/0259137	A1	11/2006	Artof et al.
2006/0265056	A1	11/2006	Nguyen et al.
2006/0271166	A1	11/2006	Thill et al.
2006/0271175	A1	11/2006	Woolfson et al.
2006/0276874	A1	12/2006	Wilson et al.
2006/0282161	A1	12/2006	Huynh et al.
2007/0005129	A1	1/2007	Damm et al.
2007/0005131	A1	1/2007	Taylor
2007/0010878	A1	1/2007	Raffiee et al.
2007/0016286	A1	1/2007	Case et al.
2007/0027518	A1	2/2007	Herrmann et al.
2007/0027533	A1	2/2007	Douk
2007/0043435	A1	2/2007	Seguin et al.
2007/0051377	A1	3/2007	Douk et al.
2007/0073392	A1	3/2007	Heyninck-Janitz
2007/0078509	A1	4/2007	Lotfy et al.
2007/0078510	A1	4/2007	Ryan
2007/0088431	A1	4/2007	Bourang et al.
2007/0093869	A1	4/2007	Bloom et al.
2007/0100439	A1	5/2007	Cangialosi
2007/0100440	A1	5/2007	Figulla
2007/0100449	A1	5/2007	O'Neil et al.
2007/0112415	A1	5/2007	Bartlett
2007/0162102	A1	7/2007	Ryan et al.
2007/0162113	A1	7/2007	Sharkawy et al.
2007/0185513	A1	8/2007	Woolfson et al.
2007/0203391	A1	8/2007	Bloom et al.
2007/0225681	A1	9/2007	House
2007/0232898	A1	10/2007	Huynh et al.
2007/0233228	A1	10/2007	Eberhardt et al.
2007/0233237	A1	10/2007	Krivoruchko
2007/0233238	A1	10/2007	Huynh et al.
2007/0238979	A1	10/2007	Huynh et al.
2007/0239254	A1	10/2007	Marchand et al.
2007/0239265	A1	10/2007	Birdsall
2007/0239266	A1	10/2007	Birdsall
2007/0239269	A1	10/2007	Dolan et al.
2007/0239271	A1	10/2007	Nguyen
2007/0239273	A1	10/2007	Allen
2007/0244544	A1	10/2007	Birdsall et al.
2007/0244545	A1	10/2007	Birdsall et al.
2007/0244546	A1	10/2007	Francis
2007/0244553	A1	10/2007	Rafiee et al.
2007/0244554	A1	10/2007	Rafiee et al.
2007/0244555	A1	10/2007	Rafiee et al.
2007/0244556	A1	10/2007	Rafiee et al.
2007/0244557	A1	10/2007	Rafiee et al.
2007/0250160	A1	10/2007	Rafiee
2007/0255394	A1	11/2007	Ryan
2007/0255396	A1	11/2007	Douk et al.
2007/0288000	A1	12/2007	Bonan
2008/0004696	A1	1/2008	Vesely
2008/0009940	A1	1/2008	Cribier
2008/0015671	A1	1/2008	Bonhoeffer
2008/0021552	A1	1/2008	Gabbay
2008/0048656	A1	2/2008	Tan
2008/0065001	A1	3/2008	Marchand et al.
2008/0065206	A1	3/2008	Liddicoat
2008/0071361	A1	3/2008	Tuval et al.
2008/0071362	A1	3/2008	Tuval et al.
2008/0071363	A1	3/2008	Tuval et al.
2008/0071366	A1	3/2008	Tuval et al.
2008/0071368	A1	3/2008	Tuval et al.
2008/0077234	A1	3/2008	Styrc
2008/0082165	A1	4/2008	Wilson et al.
2008/0082166	A1	4/2008	Styrc et al.
2008/0133003	A1	6/2008	Seguin et al.
2008/0140189	A1	6/2008	Nguyen et al.
2008/0147105	A1	6/2008	Wilson et al.
2008/0147180	A1	6/2008	Ghione et al.
2008/0147181	A1	6/2008	Ghione et al.
2008/0147182	A1	6/2008	Righini et al.
2008/0154356	A1	6/2008	Obermiller et al.
2008/0161910	A1	7/2008	Revuelta et al.
2008/0161911	A1	7/2008	Revuelta et al.
2008/0183273	A1	7/2008	Mesana et al.
2008/0188928	A1	8/2008	Salahieh et al.
2008/0215143	A1	9/2008	Seguin et al.
2008/0215144	A1	9/2008	Ryan et al.
2008/0228254	A1	9/2008	Ryan
2008/0228263	A1	9/2008	Ryan
2008/0234797	A1	9/2008	Stryc
2008/0243246	A1	10/2008	Ryan et al.
2008/0255651	A1	10/2008	Dwork
2008/0255660	A1	10/2008	Guyenot et al.
2008/0255661	A1	10/2008	Straubinger et al.
2008/0262593	A1	10/2008	Ryan et al.
2009/0005863	A1	1/2009	Goetz et al.
2009/0012600	A1	1/2009	Styrc et al.
2009/0048656	A1	2/2009	Wen
2009/0054976	A1	2/2009	Tuval et al.
2009/0069886	A1	3/2009	Suri et al.
2009/0069887	A1	3/2009	Righini et al.
2009/0069889	A1	3/2009	Suri et al.
2009/0138079	A1	5/2009	Tuval et al.
2009/0164004	A1	6/2009	Cohn
2009/0164006	A1	6/2009	Seguin et al.
2009/0171447	A1	7/2009	VonSeggesser
2009/0192585	A1	7/2009	Bloom et al.
2009/0192586	A1	7/2009	Tabor et al.
2009/0192591	A1	7/2009	Ryan et al.
2009/0198316	A1	8/2009	Laske et al.
2009/0216310	A1	8/2009	Straubinger et al.
2009/0216312	A1	8/2009	Straubinger et al.
2009/0216313	A1	8/2009	Straubinger et al.
2009/0240264	A1	9/2009	Tuval et al.

2009/0240320	A1	9/2009	Tuval
2009/0281619	A1	11/2009	Le et al.
2010/0004740	A1	1/2010	Seguin et al.
2010/0030328	A1	2/2010	Seguin et al.
2010/0036485	A1	2/2010	Seguin
2010/0069852	A1	3/2010	Kelley
2010/0094411	A1	4/2010	Tuval et al.
2010/0100167	A1	4/2010	Bortlein et al.
2010/0131054	A1	5/2010	Tuval et al.
2010/0137979	A1	6/2010	Tuval et al.
2010/0145439	A1	6/2010	Seguin et al.
2010/0152840	A1	6/2010	Seguin et al.
2010/0198346	A1	8/2010	Keogh et al.
2010/0234940	A1	9/2010	Dolan
2010/0256723	A1	10/2010	Murray

FOREIGN PATENT DOCUMENTS

DE	195 46 692	C2	6/1997
DE	195 46692	A1	6/1997
DE	198 57 887	A1	7/2000
DE	199 07 646		8/2000
DE	100 48 814		9/2000
DE	10010074		10/2001
DE	100 49 812		4/2002
DE	100 49 813		4/2002
DE	100 49 815		4/2002
EP	0103546		3/1984
EP	0597967		12/1994
EP	0850607		7/1998
EP	1057459	A1	6/2000
EP	1057460	A1	6/2000
EP	1088529		4/2001
EP	1255510		11/2002
EP	0937439	B1	9/2003
EP	1340473		9/2003
EP	0819013		6/2004
FR	2 800 984		11/1999
FR	2788217		12/1999
FR	2 815 844		10/2000
GB	2056023		3/1981
GB	2433700		12/2007
SU	1271508		11/1986
WO	91/017720		11/1991
WO	93/001768		2/1993
WO	95/29640		11/1995
WO	98/14137		4/1998
WO	98/29057		7/1998
WO	99/33414		7/1999
WO	00/41652		7/2000
WO	00/44313		8/2000
WO	00/47136		8/2000
WO	00/47139		8/2000
WO	01/35870		5/2001
WO	01/49213		7/2001
WO	01/54625		8/2001
WO	01/62189		8/2001
WO	01/64137		9/2001
WO	01/76510		10/2001
WO	02/22054		3/2002
WO	02/36048		5/2002
WO	02/41789		5/2002
WO	02/43620		6/2002
WO	02/47575		6/2002
WO	02/49540		6/2002
WO	03/003943		1/2003
WO	03/003949		1/2003
WO	03/011195		2/2003
WO	03/030776		4/2003
WO	2004/019811		3/2004
WO	2004/019825		3/2004
WO	2004/023980		3/2004
WO	2004/041126		5/2004
WO	2004/058106		7/2004
WO	2004/089250		10/2004
WO	2005/004753		1/2005
WO	2005/027790		3/2005
WO	2005/046528		5/2005
WO	2008/047354		4/2008
WO	2008/100599		8/2008
WO	2008/150529		12/2008
WO	2009/002548		12/2008
WO	2009/045338		4/2009
WO	2009/061389		5/2009
WO	2009/091509		7/2009

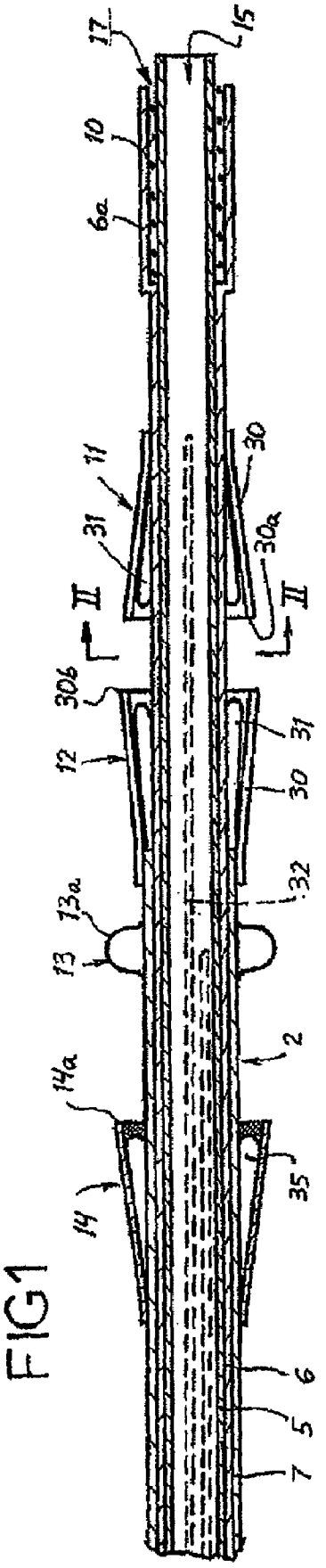
OTHER PUBLICATIONS

U.S. Appl. No. 61/192,199, filed Sep. 15, 2008.
U.S. Appl. No. 12/253,858, filed Oct. 17, 2008.
U.S. Appl. No. 12/596,343, filed Apr. 14, 2008.
U.S. Appl. No. 61/129,170, filed Jun. 9, 2008.
Andersen, H.R. et al, "Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs." Euro. Heart J. (1992) 13:704-708.
Babaliaros, et al., "State of the Art Percutaneous Intervention for the Treatment of Valvular Heart Disease: A Review of the Current Technologies and Ongoing Research in the Field of Percutaneous Heart Valve Replacement and Repair," Cardiology 2007; 107:87-96.
Bailey, "Percutaneous Expandable Prosthetic Valves," in: Topol EJ, ed. Textbook of Interventional Cardiology. vol. II. Second edition. WB Saunders, Philadelphia, 1994:1268-1276.
Block, et al., "Percutaneous Approaches to Valvular Heart Disease," Current Cardiology Reports, vol. 7 (2005) pp. 108-113.
Bonhoeffer, et al, "Percutaneous Insertion of the Pulmonary Valve," Journal of the American College of Cardiology (United States), May 15, 2002, pp. 1664-1669.
Bonhoeffer, et al, "Percutaneous Mitral Valve Dilatation with the Multi-Track System," Catheterization and Cardiovascular Interventions—Official Journal of the Society for Cardiac Angiography & Interventions (United States), Oct. 1999, pp. 178-183.
Bonhoeffer, et al, "Percutaneous Replacement of Pulmonary Valve in a Right-Ventricle to Pulmonary-Artery Prosthetic Conduit with Valve Dysfunction," Lancet (England), Oct. 21, 2000, pp. 1403-1405.
Bonhoeffer, et al, "Technique and Results of Percutaneous Mitral Valvuloplasty With the Multi-Track System," Journal of Interventional Cardiology (United States), 200, pp. 263-268.
Bonhoeffer, et al, "Transcatheter Implantation of a Bovine Valve in Pulmonary Position: a Lamb Study," Circulation (United States), Aug. 15, 2000, pp. 813-816.
Boudjemline, et al, "Images in Cardiovascular Medicine. Percutaneous Aortic Valve Replacement in Animals," Circulation (United States), Mar. 16, 2004, 109, p. e161.
Boudjemline, et al, "Is Percutaneous Implantation of a Bovine Venous Valve in the Inferior Vena Cava a Reliable Technique to Treat Chronic Venous Insufficiency Syndrome?" Medical Science Monitor—International Medical Journal of Experimental and Clinical Research (Poland), Mar. 2004, pp. BR61-BR66.
Boudjemline, et al, "Off-pump Replacement of the Pulmonary Valve in Large Right Ventricular Outflow Tracts: a Hybrid Approach," Journal of Thoracic and Cardiovascular Surgery (United States), Apr. 2005, pp. 831-837.

Boudjemline, et al, "Percutaneous Aortic Valve Replacement: Will We Get There?" Heart (British Cardiac Society) (England), Dec. 2001, pp. 705-706.
Boudjemline, et al, "Percutaneous Closure of a Paravalvular Mitral Regurgitation with Amplatzer and Coil Prostheses," Archives des Maladies du Coeur Et Des Vaisseaux (France), May 2002, pp. 483-486.
Boudjemline, et al, "Percutaneous Implantation of a Biological Valve in the Aorta to Treat Aortic Valve Insufficiency—a Sheep Study," Medical Science Monitor—International Medical Journal of Experimental and Clinical Research (Poland), Apr. 2002, pp. BR113-BR116.
Boudjemline, et al, "Percutaneous Implantation of a Biological Valve in Aortic Position: Preliminary Results in a Sheep Study," European Heart Journal 22, Sep. 2001, p. 630.
Boudjemline, et al, "Percutaneous Implantation of a Valve in the Descending Aorta in Lambs," European Heart Journal (England), Jul. 2002, pp. 1045-1049.
Boudjemline, et al, "Percutaneous Pulmonary Valve Replacement in a Large Right Ventricular Outflow Tract: an Experimental Study," Journal of the American College of Cardiology (United States), Mar. 17, 2004, pp. 1082-1087.
Boudjemline, et al, "Percutaneous Valve Insertion: a New Approach," Journal of Thoracic and Cardiovascular Surgery (United States), Mar. 2003, pp. 741-742.
Boudjemline, et al, "Stent Implantation Combined with a Valve Replacement to Treat Degenerated Right Ventricle to Pulmonary Artery Prosthetic Conduits," European Heart Journal 22, Sep. 2001, p. 355.
Boudjemline, et al, "Steps Toward Percutaneous Aortic Valve Replacement," Circulation (United States), Feb. 12, 2002, pp. 775-778.
Boudjemline, et al, "The Percutaneous Implantable Heart Valve," Progress in Pediatric Cardiology (Ireland), 2001, pp. 89-93.
Boudjemline, et al, "Transcatheter Reconstruction of the Right Heart," Cardiology in the Young (England), Jun. 2003, pp. 308-311.
Coats, et al, "The Potential Impact of Percutaneous Pulmonary Valve Stent Implantation on Right Ventricular Outflow Tract Re-Intervention," European Journal of Cardio-Thoracic Surgery (England), Apr. 2005, pp. 536-543.
Cribier, A. et al, "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis: First Human Case Description," Circulation (2002) 3006-3008.
Davidson et al., "Percutaneous therapies for valvular heart disease," Cardiovascular Pathology 15 (2006) 123-129.
Hanzel, et al., "Complications of percutaneous aortic valve replacement: experience with the Criber-Edwards™ percutaneous heart valve," EuroIntervention Supplements (2006), I (Supplement A) A3-A8.
Huber, et al., "Do Valved Stents Compromise Coronary Flow?" Eur. J. Cardiothorac. Surg. 2004;25:754-759.
Khambadkone, "Nonsurgical Pulmonary Valve Replacement: Why, When, and How?" Catheterization and Cardiovascular Interventions—Official Journal of the Society for Cardiac Angiography & Interventions (United States), Jul. 2004, pp. 401-408.
Khambadkone, et al, "Percutaneous Implantation of Pulmonary Valves," Expert Review of Cardiovascular Therapy (England), Nov. 2003, pp. 541-548.
Khambadkone, et al, "Percutaneous Pulmonary Valve Implantation: Early and Medium Term Results," Circulation 108 (17 Supplement), Oct. 28, 2003, p. IV-375.
Khambadkone, et al, "Percutaneous Pulmonary Valve Implantation: Impact of Morphology on Case Selection," Circulation 108 (17 Supplement), Oct. 28, 2003, p. IV-642-IV-643.
Lutter, et al, "Percutaneous Aortic Valve Replacement: an Experimental Study. I. Studies on Implantation," The Journal of Thoracic and Cardiovascular Surgery, Apr. 2002, pp. 768-776.
Lutter, et al, "Percutaneous Valve Replacement: Current State and Future Prospects," Annals of Thoracic Surgery (Netherlands), Dec. 2004, pp. 2199-2206.
Medtech Insight, "New Frontiers in Heart Valve Disease," vol. 7, No. 8 (2005).
Palacios, "Percutaneous Valve Replacement and Repair, Fiction or Reality?" Journal of American College of Cardiology, vol. 44, No. 8 (2004) pp. 1662-1663.
Ruiz, "Transcathether Aortic Valve Implantation and Mitral Valve Repair: State of the Art," Pediatric Cardiology, vol. 26, No. 3 (2005).
Saliba, et al, "Treatment of Obstructions of Prosthetic Conduits by Percutaneous Implantation of Stents," Archives des Maldies du Coeur et des Vaisseaux (France), 1999, pp. 591-596.
Webb, et al., "Percutaneous Aortic Valve Implantation Retrograde from the Femoral Artery," Circulation (2006), 113;842-850.
Yonga, et al, "Effect of Percutaneous Balloon Mitral Valvotomy on Pulmonary Venous Flow in Severe Mitral Stenosis," East African Medical Journal (Kenya), Jan. 1999, pp. 28-30.
Yonga, et al, "Percutaneous Balloon Mitral Valvotomy: Initial Experience in Nairobi Using a New Multi-Track Catheter System," East African Medical Journal (Kenya), Feb. 1999, pp. 71-74.
Yonga, et al, "Percutaneous Transluminal Balloon Valvuloplasty for Pulmonary Valve Stenosis: Report on Six Cases," East African Medical Journal (Kenya), Apr. 1994, pp. 232-235.
Yonga, et al, "Percutaneous Transvenous Mitral Commissurotomy in Juvenile Mitral Stenosis," East African Medical Journal (Kenya), Apr. 2003, pp. 172-174.
Commeau et al, "Percutaneous balloon dilatation of calcific aortic valve stenosis: anatomical and haemodynamic evaluation," 1988, British Heart Journal, 59:227-238.
Stassano et al., "Mid-term results of the valve-on-valve technique for bioprosthetic failure," Eur. J. Cardiothorac. Surg. 2000; 18:453-457.
Expert report of Dr. Nigel Buller, dated Jan. 12, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (83 pages).
Expert report of Dr. Nigel Buller, non-confidential annex—infringement, dated Jan. 12, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (12 pages).
Expert report of Dr. Rodolfo Quijano, dated Jan. 9, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (18 pages).
First Expert report of Prof. David Williams, dated Jan. 12, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (41 pages).
First Expert report of Prof. Martin Rothman, dated Jan. 12, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (64 pages).

Fourth Expert report of Prof. Martin Rothman, dated Apr. 22, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (10 pages).
Second Expert report of Dr. Nigel Buller, dated Feb. 25, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (24 pages).
Second Expert report of Dr. Rodolfo Quijano, dated Feb. 26, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (6 pages).
Second Expert report of Prof. David Williams, dated Feb. 5, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (15 pages).
Second Expert report of Prof. Martin Rothman, dated Feb. 5, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (11 pages).
Third Expert report of Dr. Nigel Buller, dated Apr. 21, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (6 pages).
Third Expert report of Dr. Rudolfo Quijano, dated Apr. 27, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (3 pages).
Third Expert report of Prof. David Williams, dated Apr. 22, 2009, Edwards' United Kingdom action for invalidity, Claim No. HC 08CO0934 (9 pages).
Pavcnik et al., "Aortic and venous valve for percutaneous insertion," Min. Invas. Ther. & Allied Techol. 2000, vol. 9, pp. 287-292.
First Expert report of Dr. Nigel Person Buller (30 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
Second Expert report of Dr. Nigel Person Buller (5 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
Drawing by Dr. Buller (Edwards Expert) of his interpretation of the "higher stent" referred to at col. 8, lines 13-222 of Andersen EP 592410B1 (1 page), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
Drawing by Dr. Buller (Edwards Expert) of "higher stent" on the schematic representation of the aortic valve area set out in Figure 2 of Rothman's first expert report (1 page), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
First Expert report of Professor John R.4 Pepper (20 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
Second Expert report of Professor John R. Pepper (3 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
First Expert report of Dr. Anthony C. Lunn (7 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
First Witness statement of Stanton Rowe (9 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
Second Witness statement of Stanton Rowe (3 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
PVT slides naming Alain Cribier, Martin Leon, Stan Rabinovich and Stanton Rowe (16 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
First Expert report of Professor Martin Terry Rothman (75 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
Reply Expert report of Professor Martin Terry Rothman (9 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
First Expert report of Richard A. Hillstead (41 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
Reply Expert report of Richard A. Hillstead (9 pages), *Corevalve, Inc.* v. *Edwards Lifesciences AG and Edwards Lifesciences PVT, Inc.*, High Court of Justice—Chancery Division Patents Court, United Kingdom, Case No. HC-07-C01243.
Pelton et al, Medical Uses of Nitinol, Materials Science Forum vols. 327-328 pp. 63-70. (2000)
Trial Transcripts, *Edwards Lifesciences AG and Edwards Lifesciences, LLC.*v. *Medtronic Core Valve LLC*, United States District Court for the District of Delaware, Civil Action No. 1:08-CV-00091-GMSM, Mar. 23, 2010-Apr. I, 2010.
Affidavit of Michael D. Gadeberg, Jul. 8, 2010-Apr. 1, 2010.
Slide Deck for Plaintiff's Closing Arguments in *Edwards Lifesciences AG and Edwards Lifesciences, LLC.* V. *Medtronic Core Valve LLC*, United States District Court for the District of Delaware, Civil Actoin No. 1:08-CV-00091-GMS, Apr. 1, 2010 (107 pages).
Response to Restriction Requirement, U.S. Appl. No. 12/823,428, dated Nov. 15, 2010 (9 pages).

* cited by examiner



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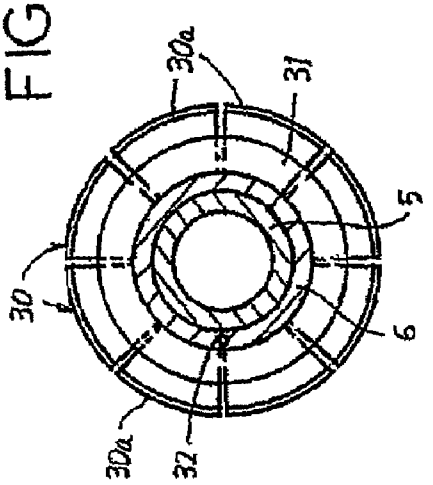

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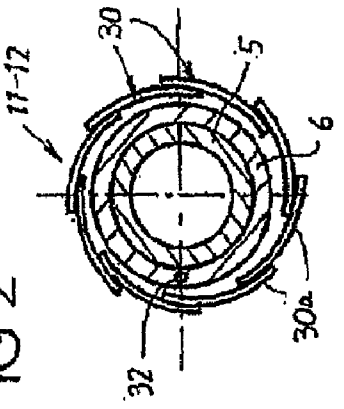

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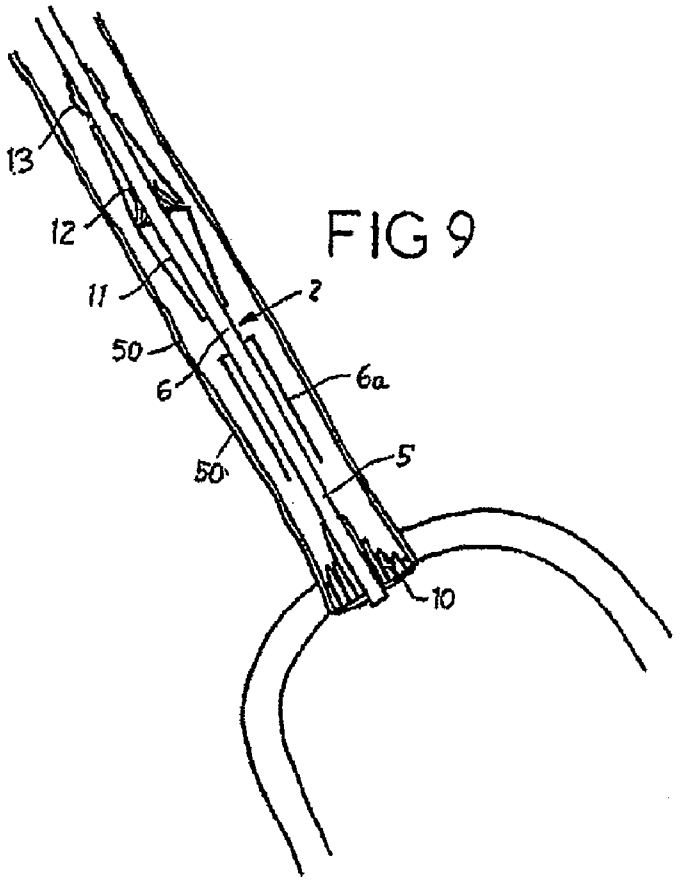

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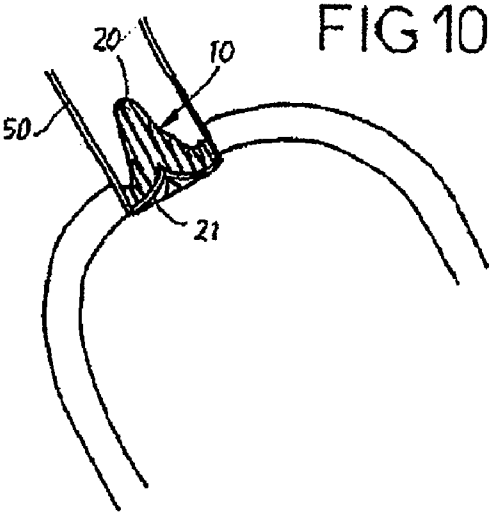

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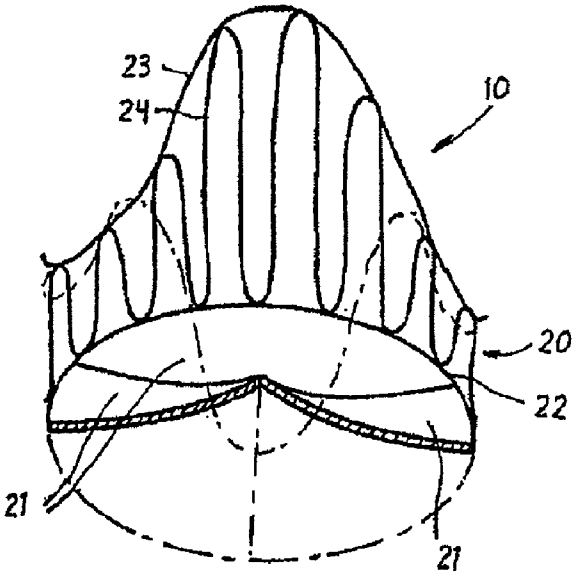

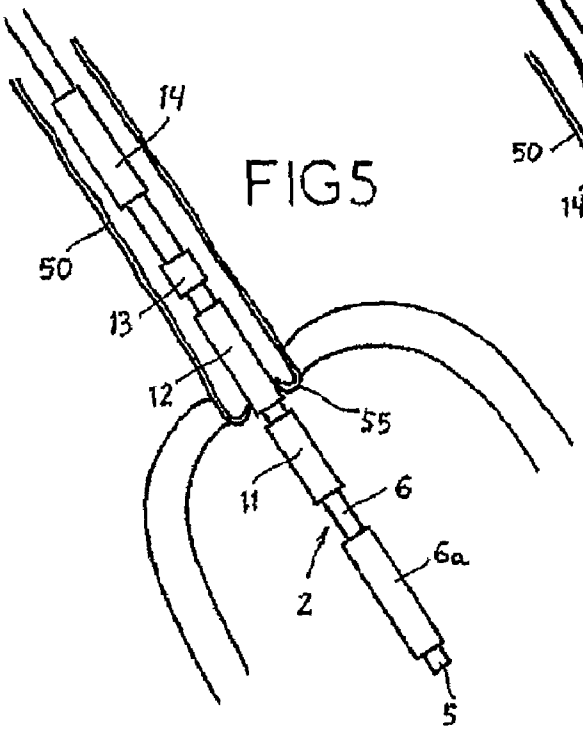

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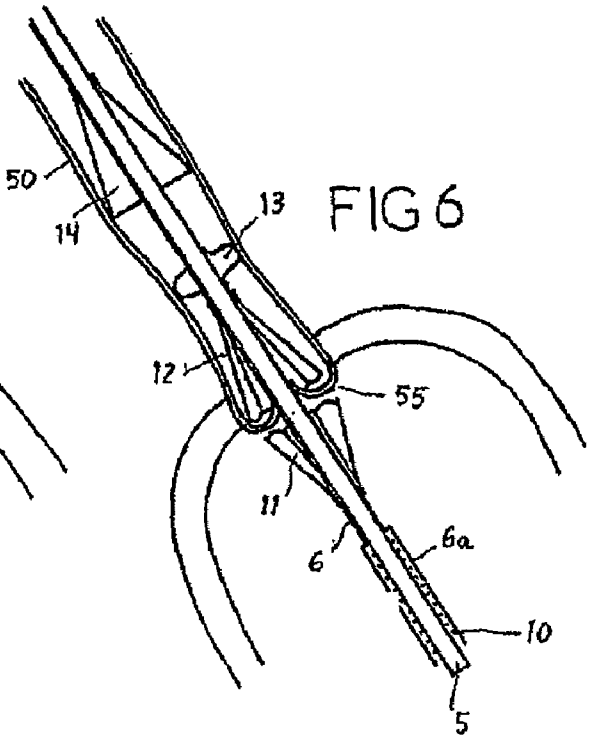

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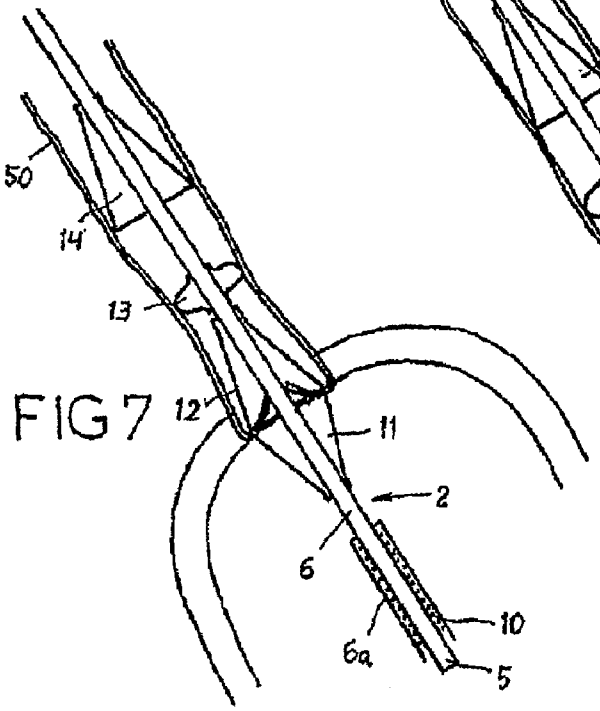

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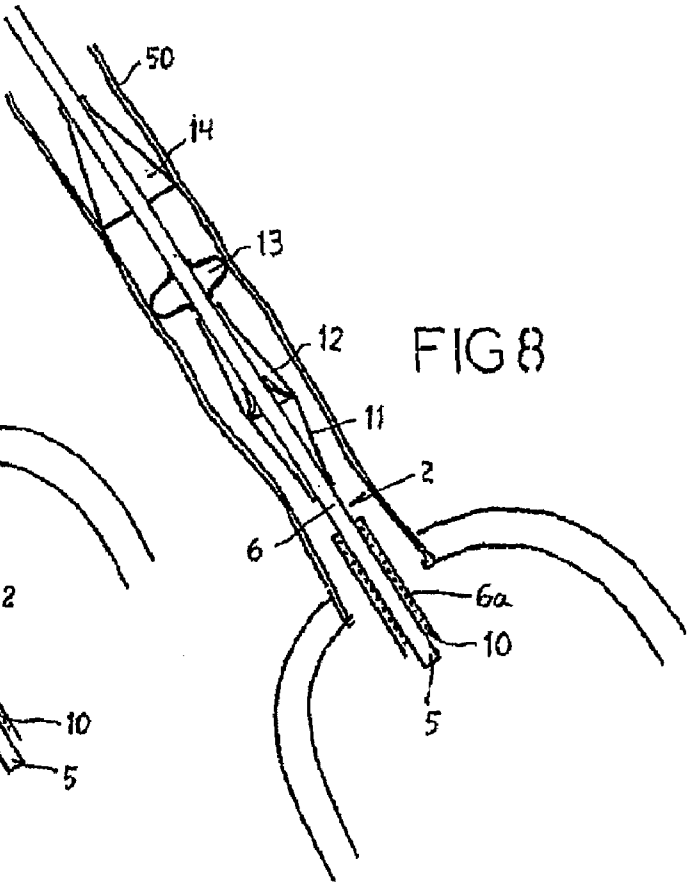

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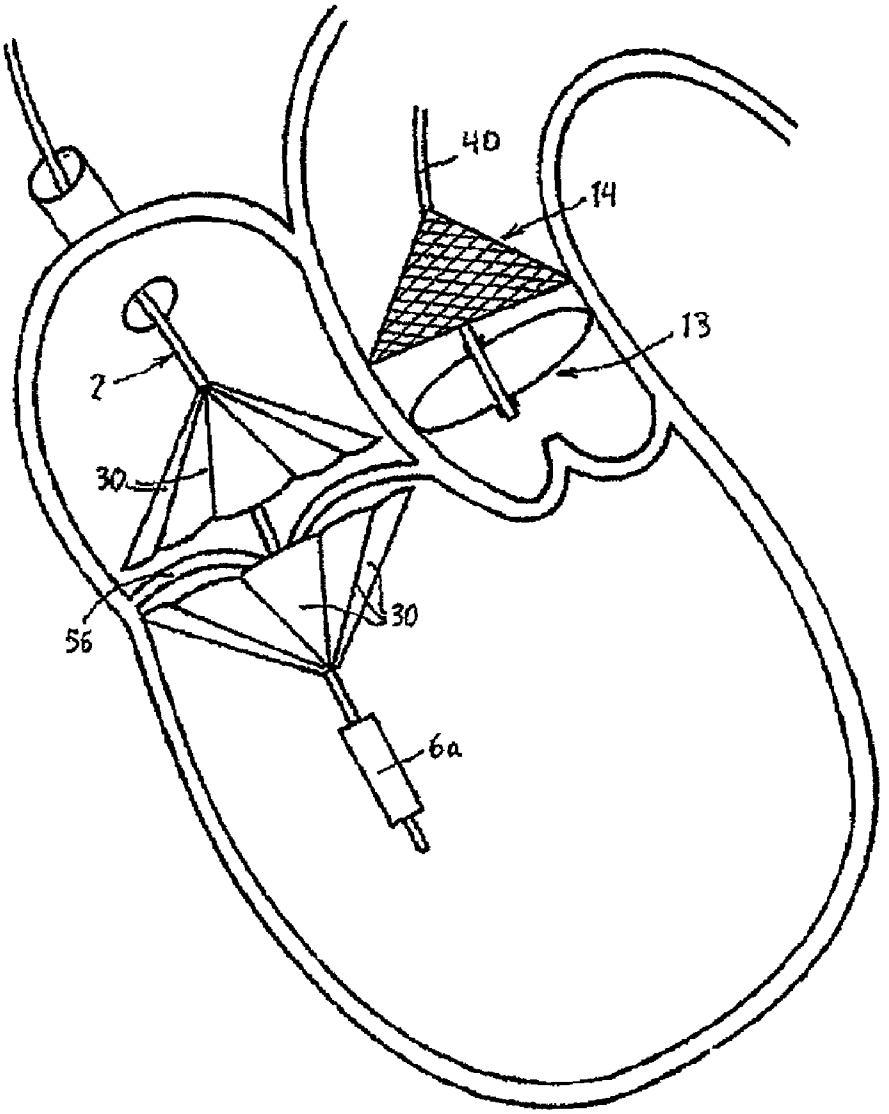

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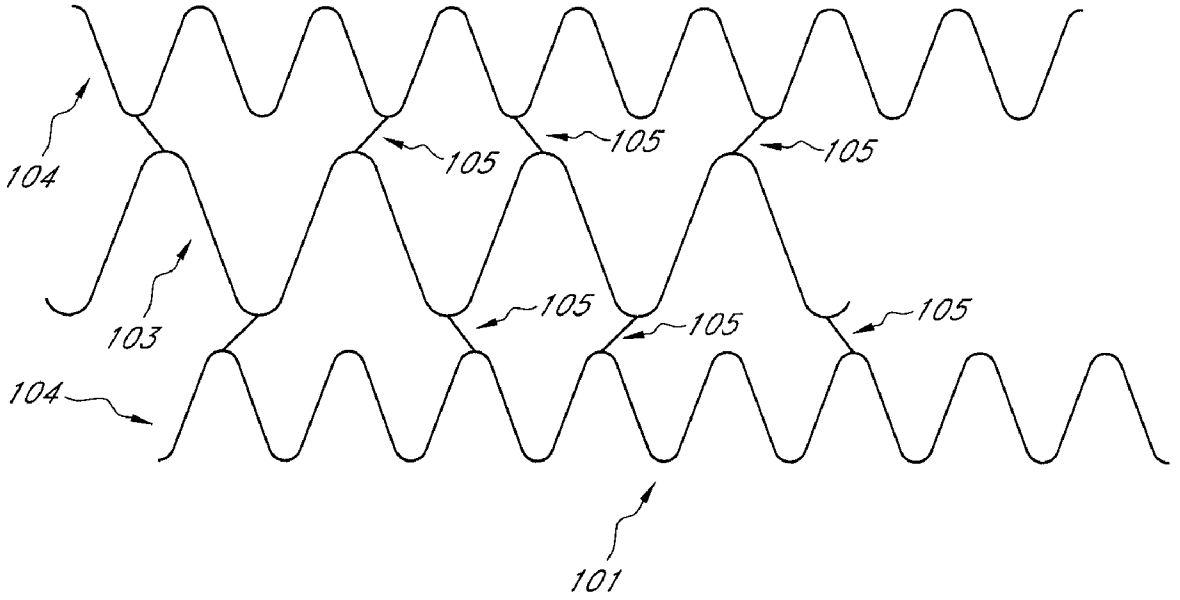
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FIG. 13

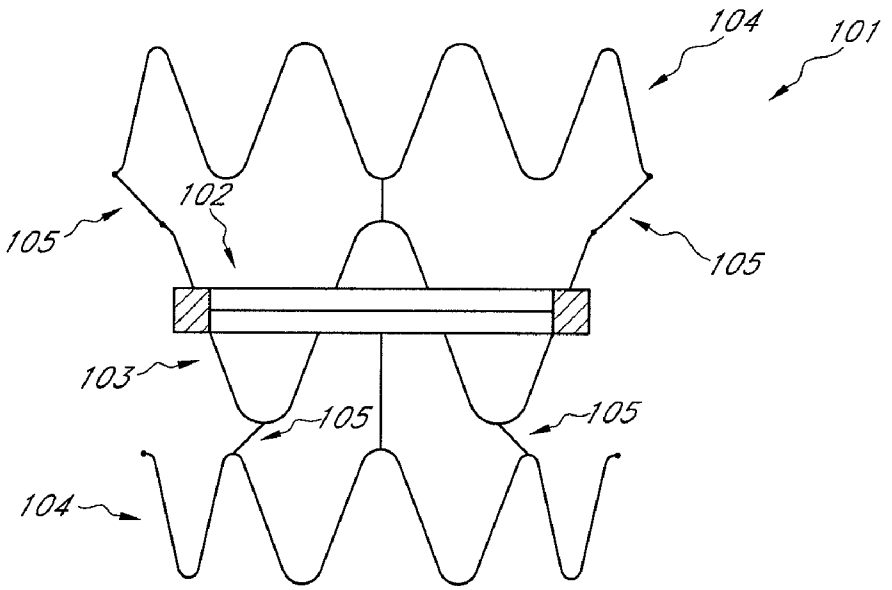
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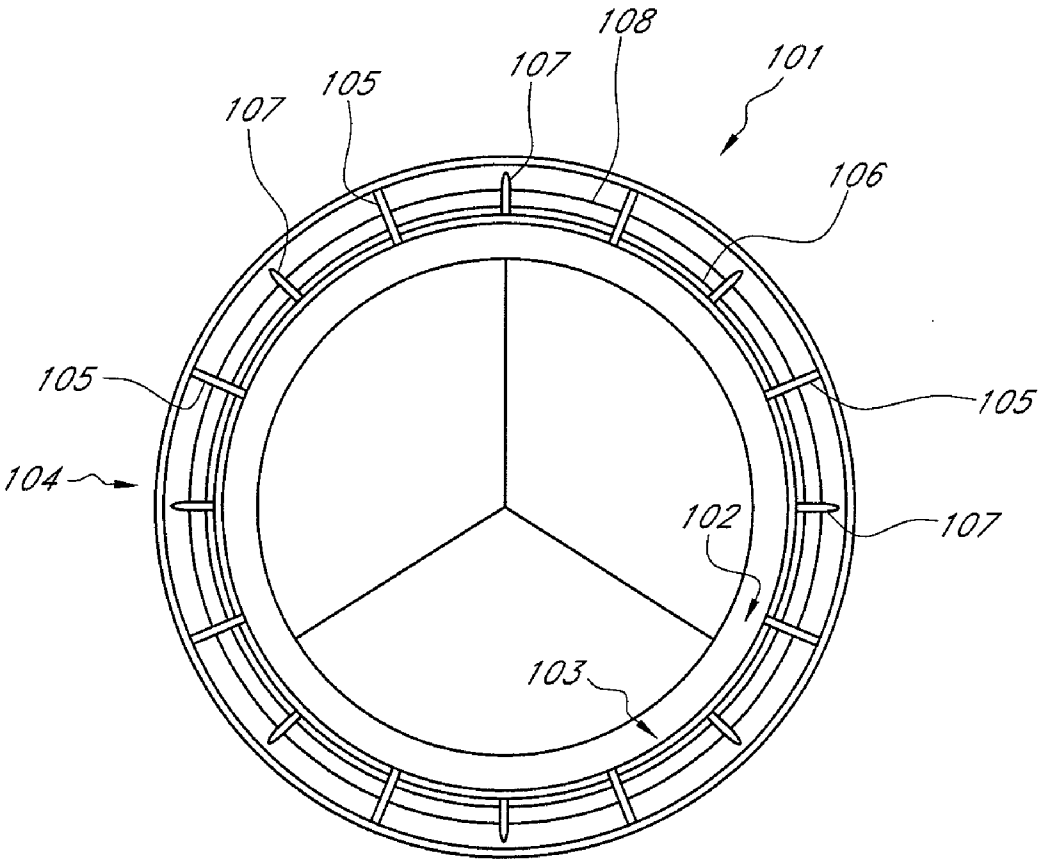
FIG. 14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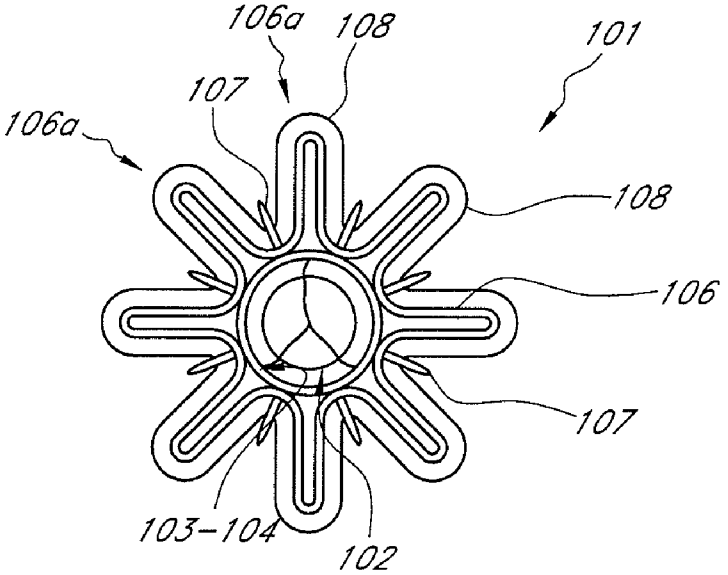
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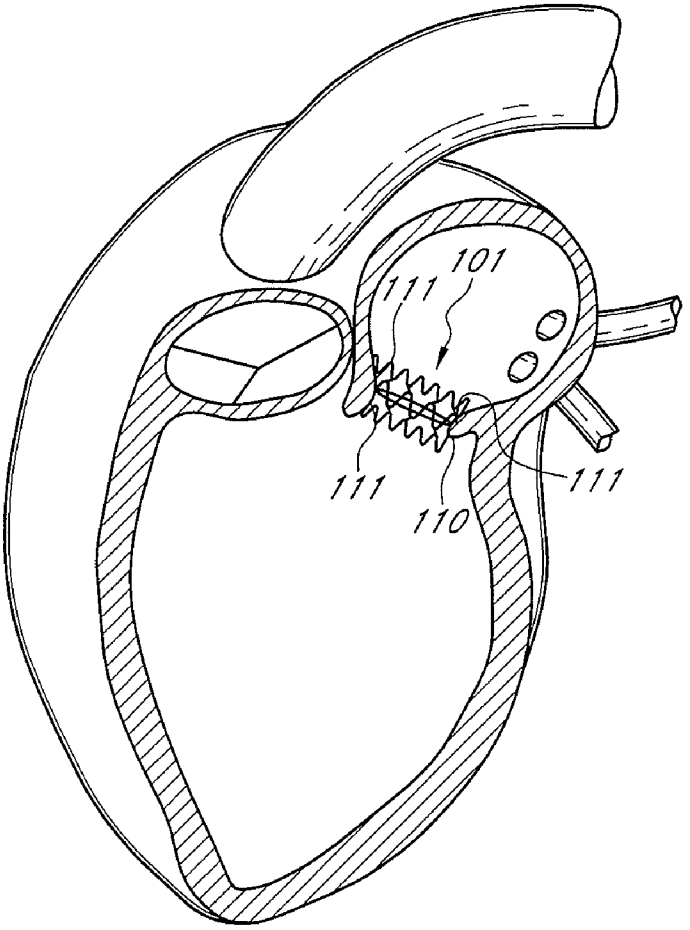
FIG. 16



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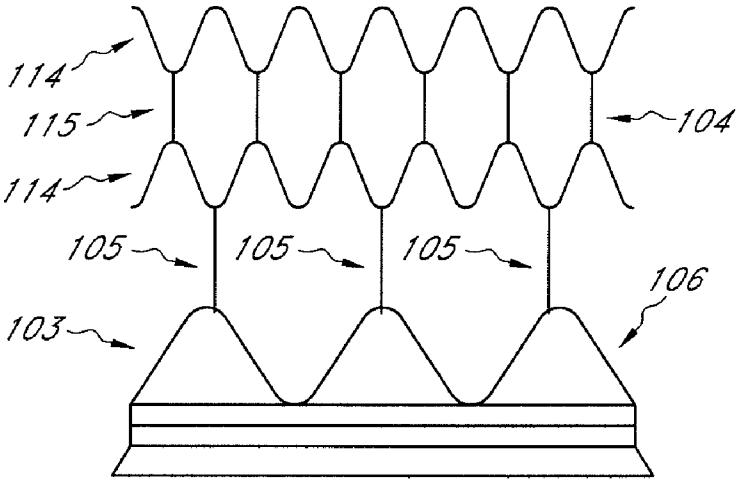

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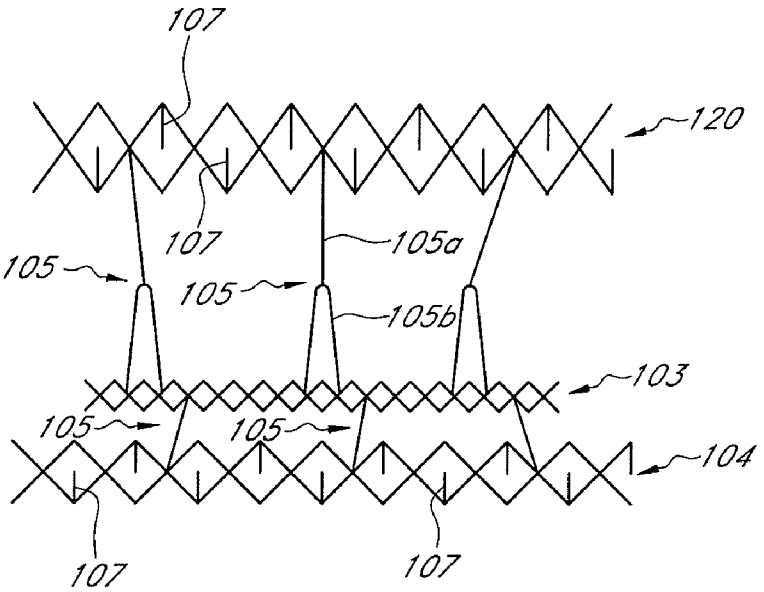
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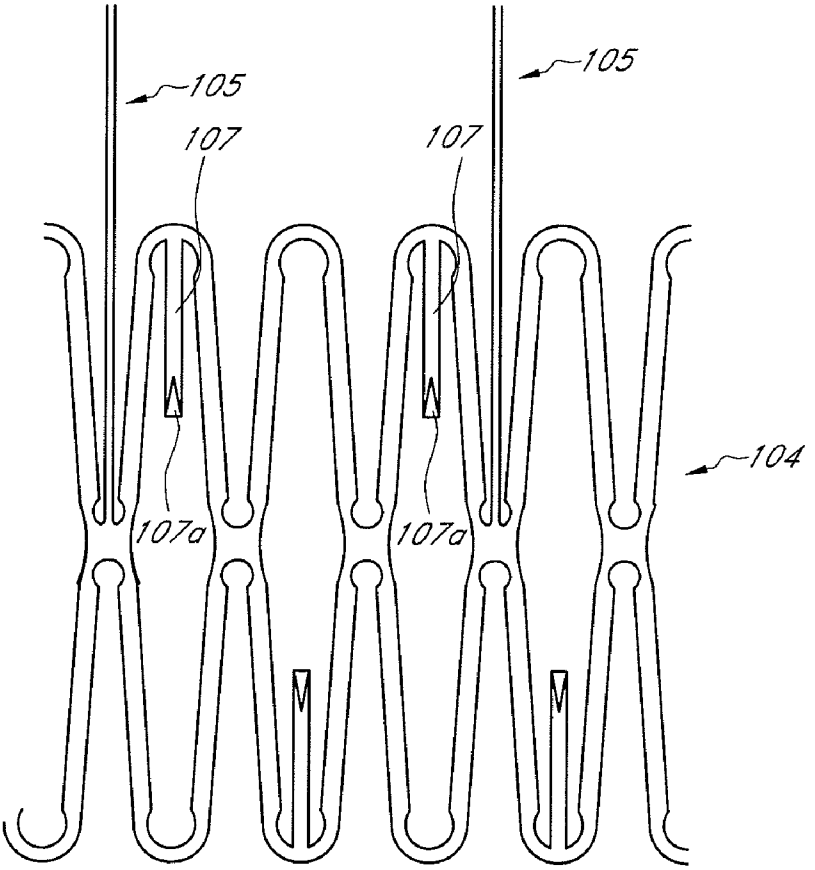
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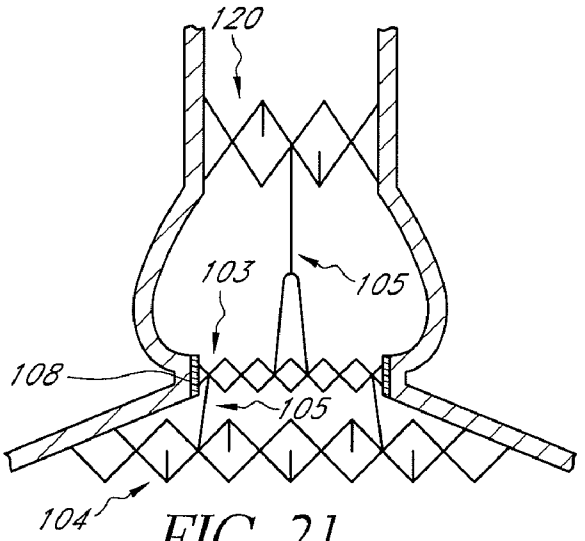
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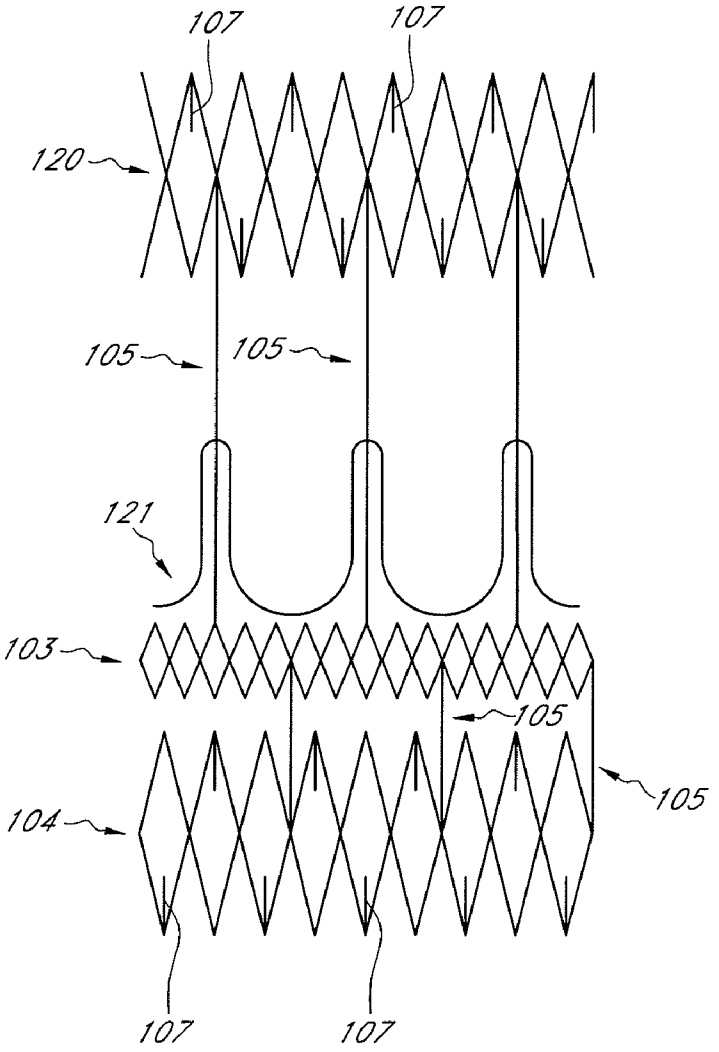
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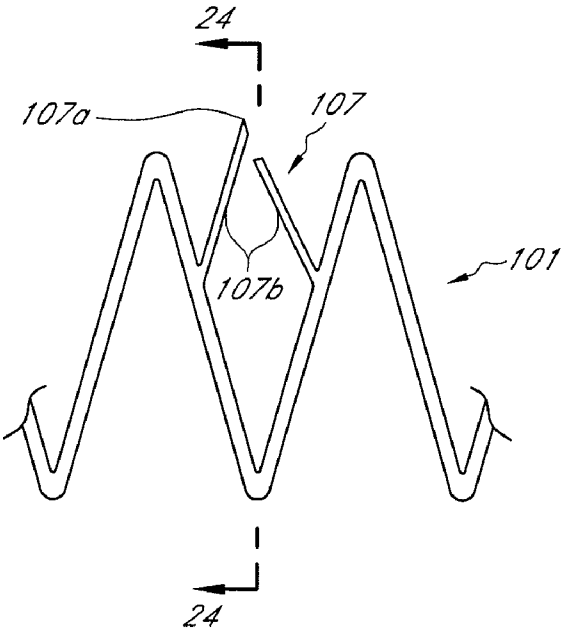

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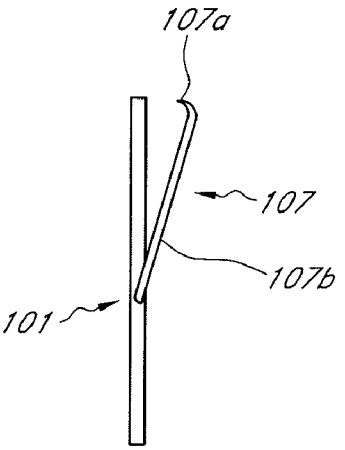

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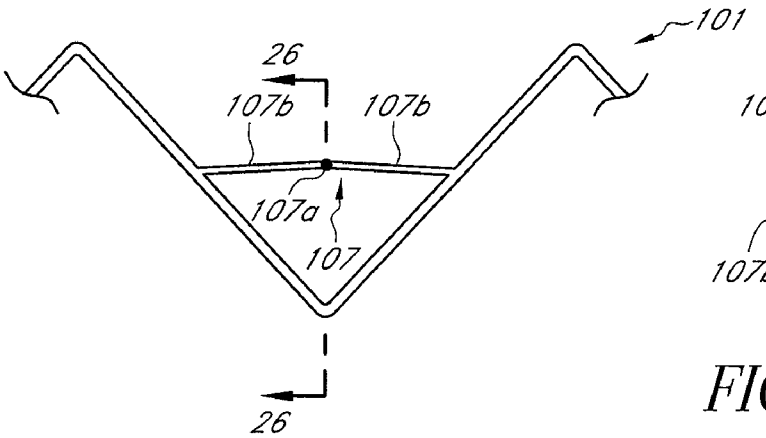

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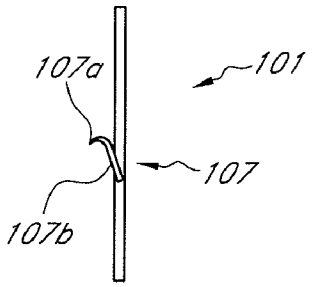

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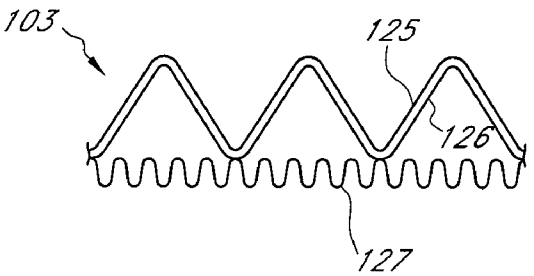

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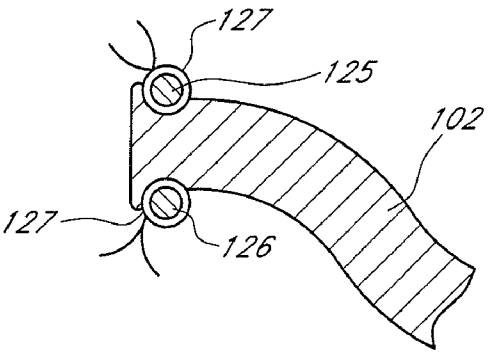

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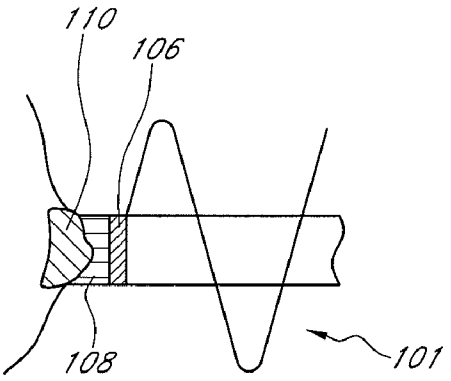

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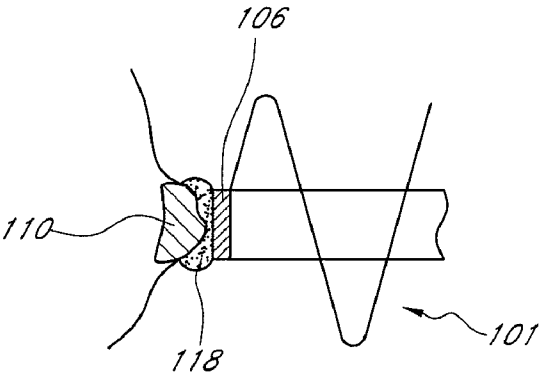

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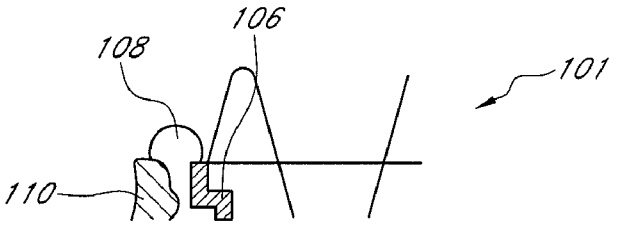

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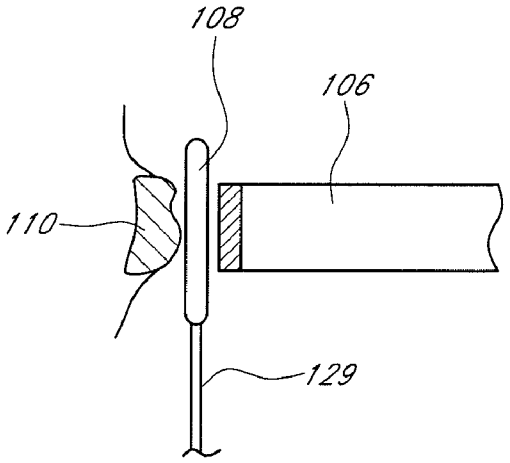

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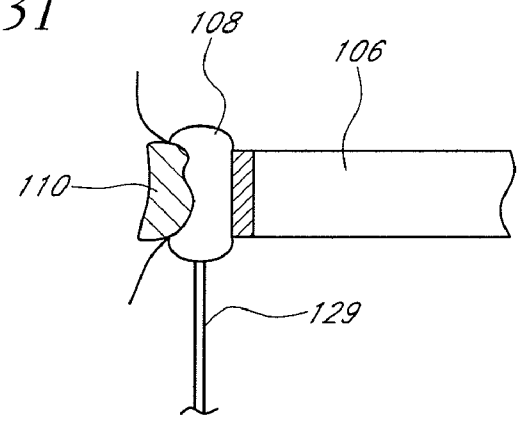

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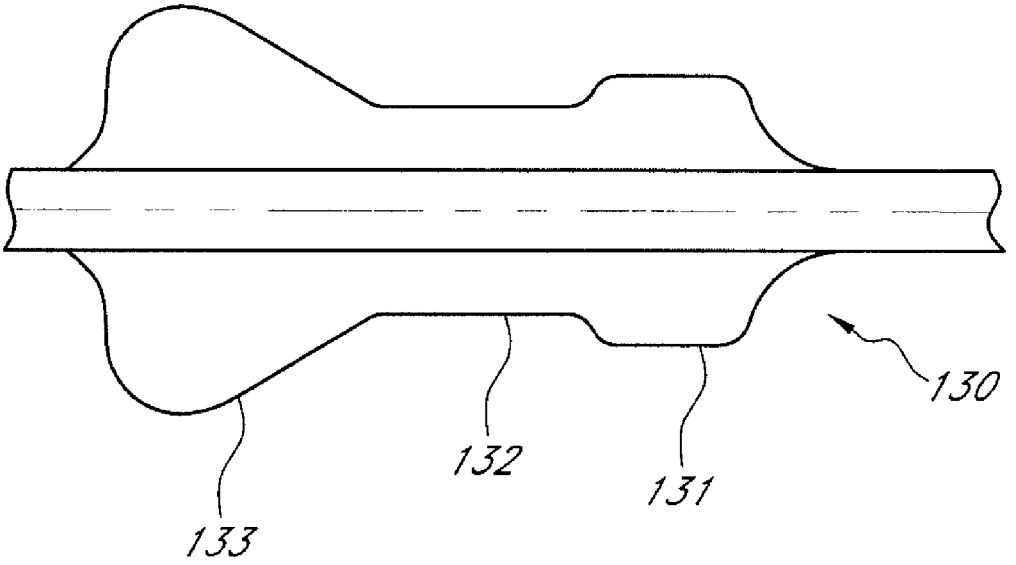

FIG. 34

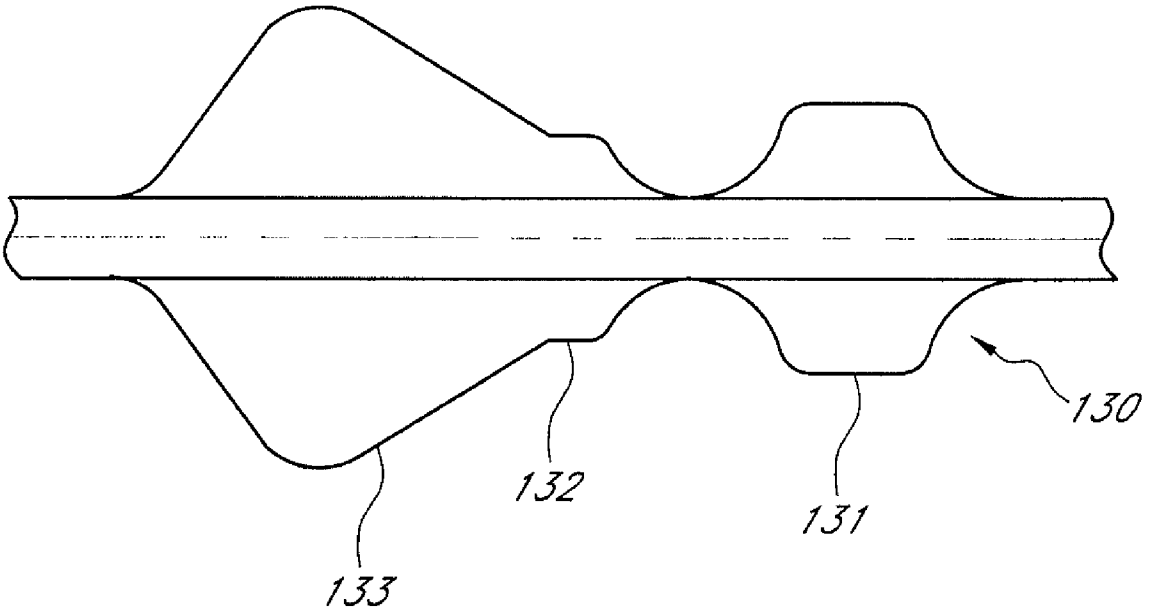

FIG. 35

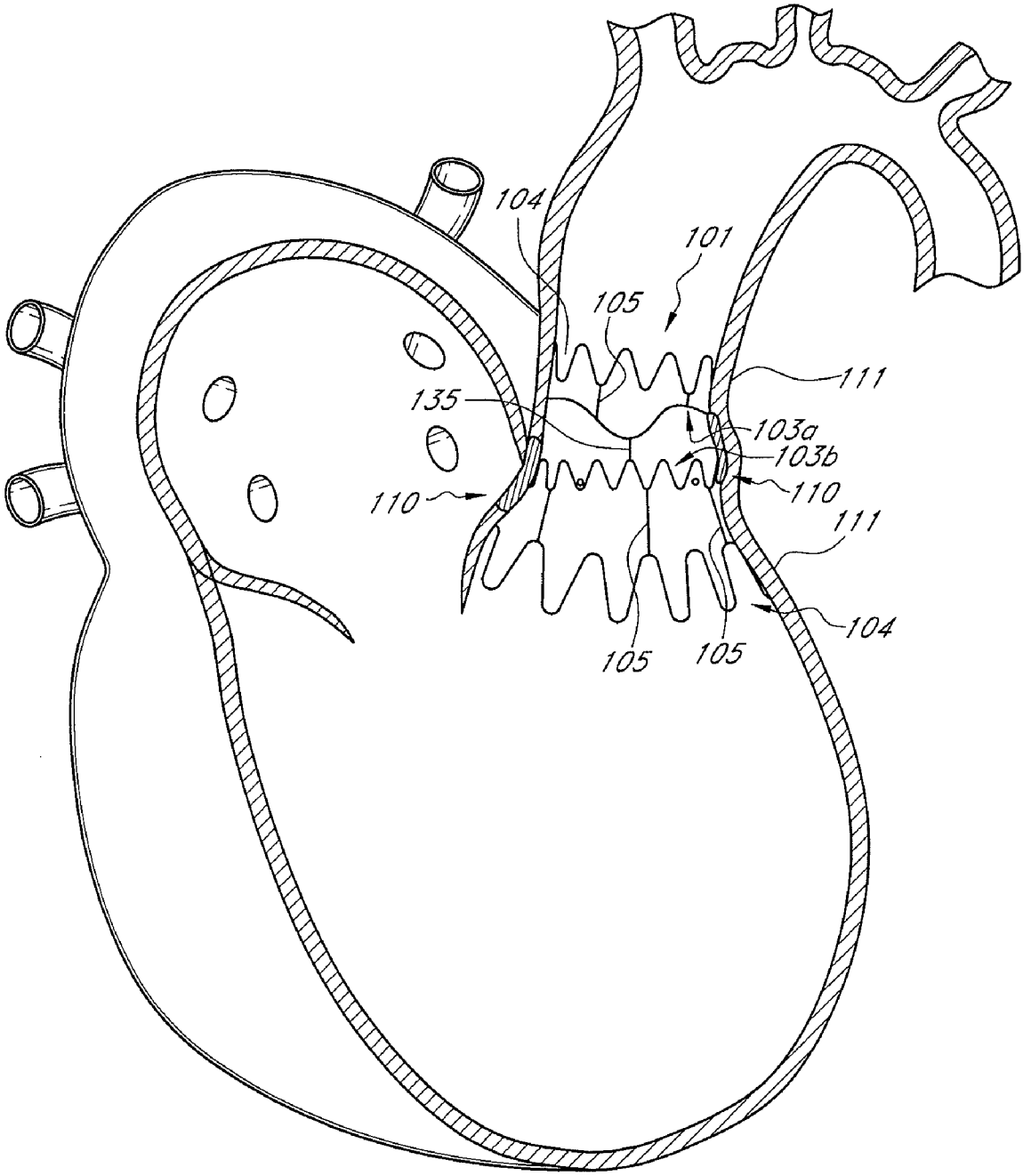

FIG. 36

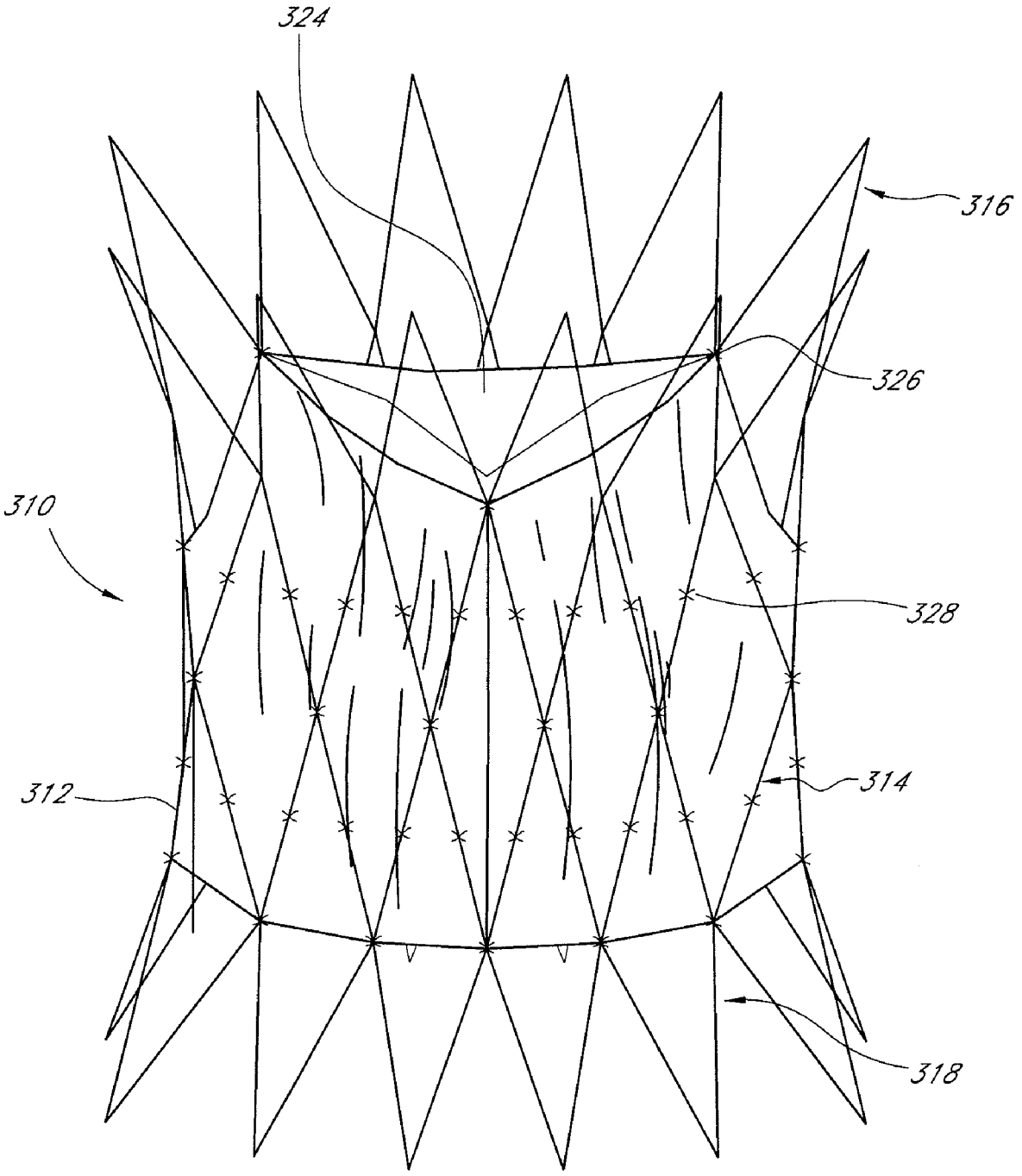

FIG. 37

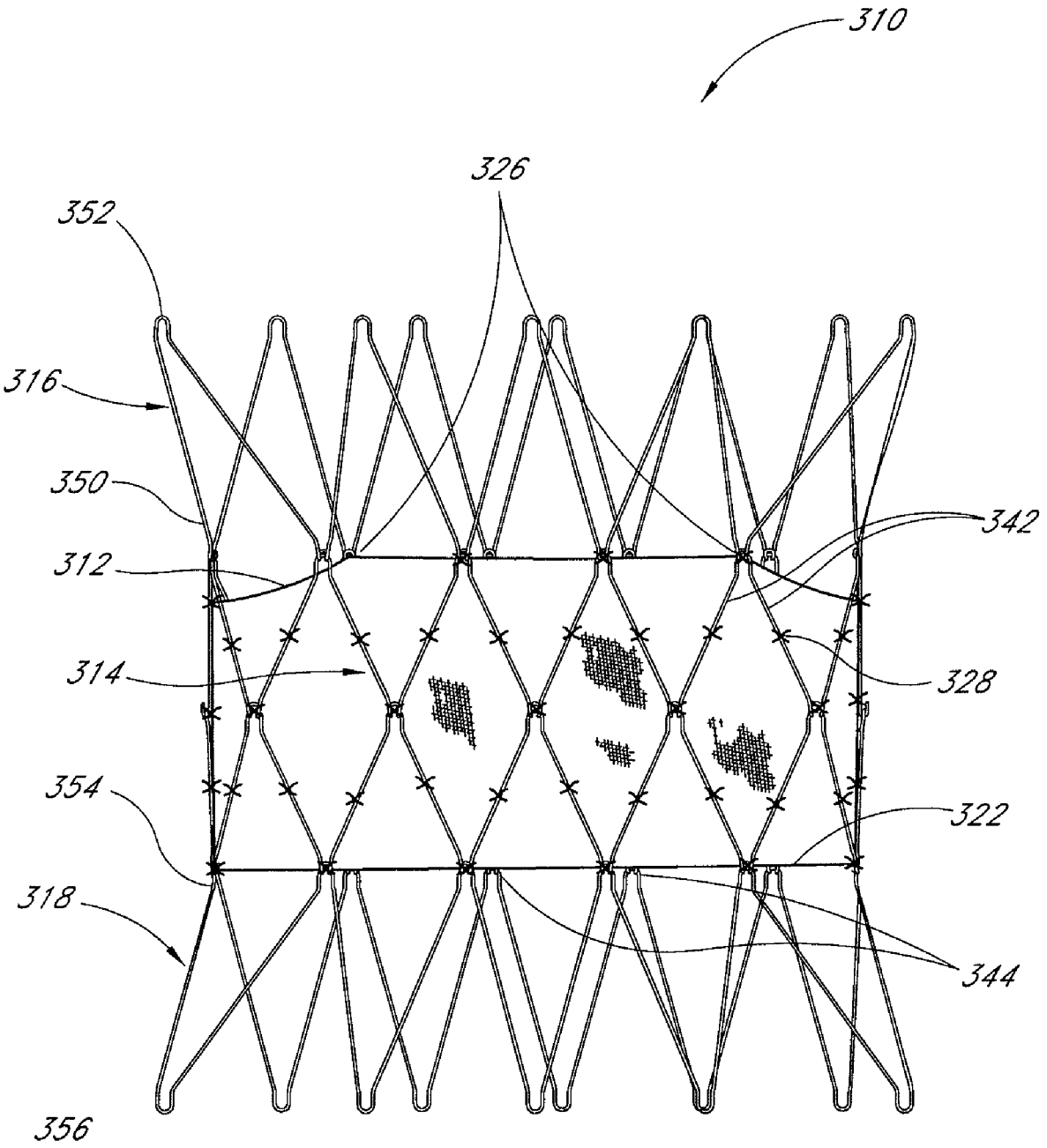

FIG. 38

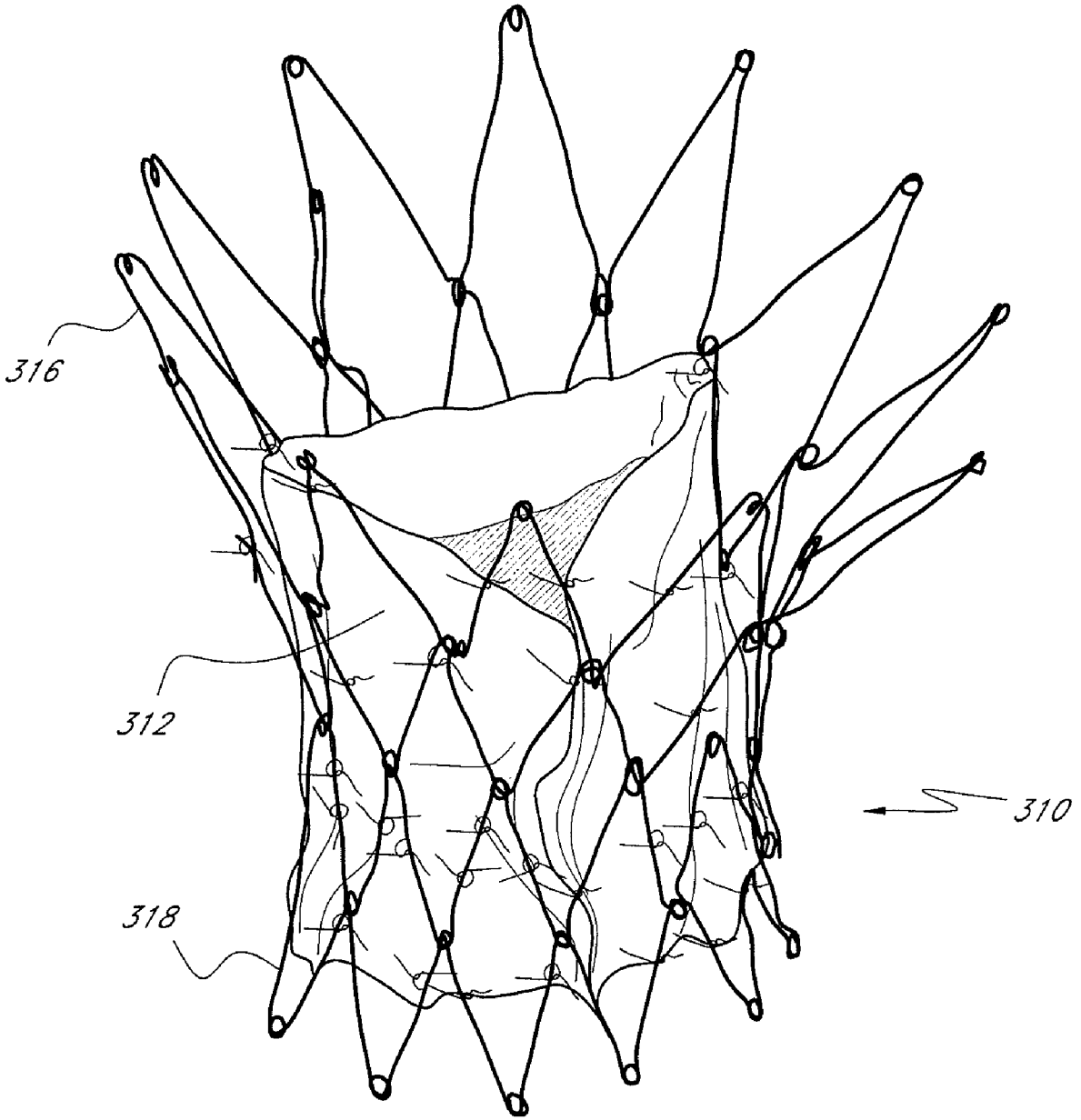

FIG. 39

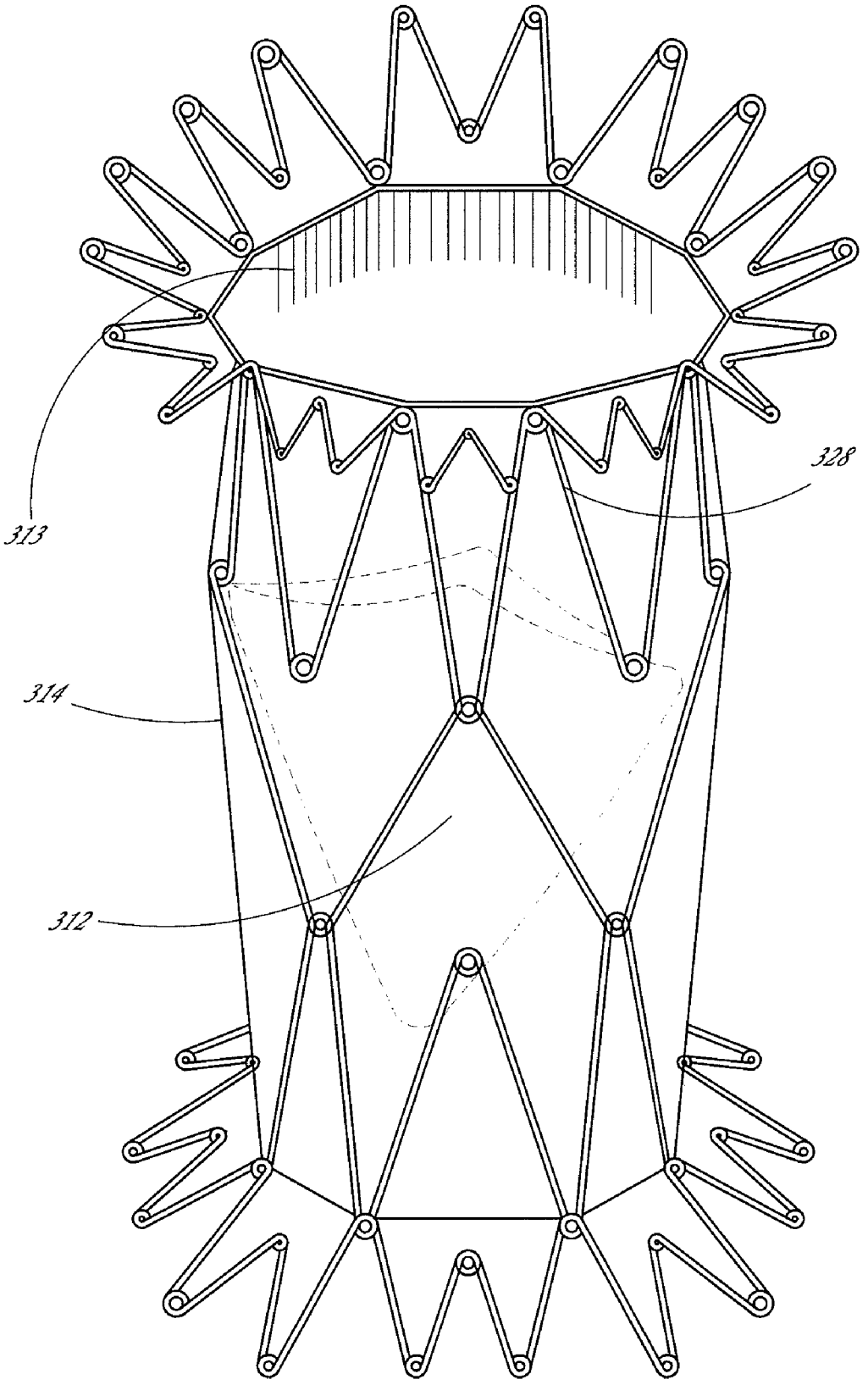

FIG. 40

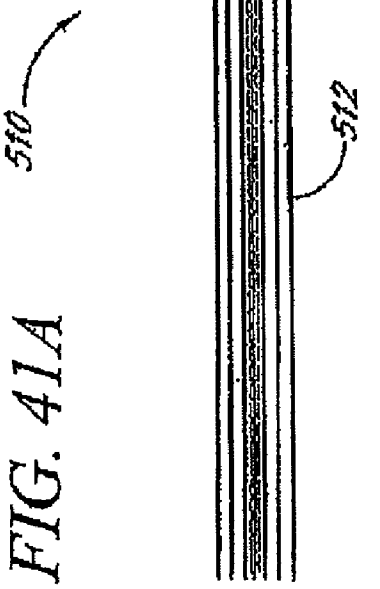

FIG. 41A

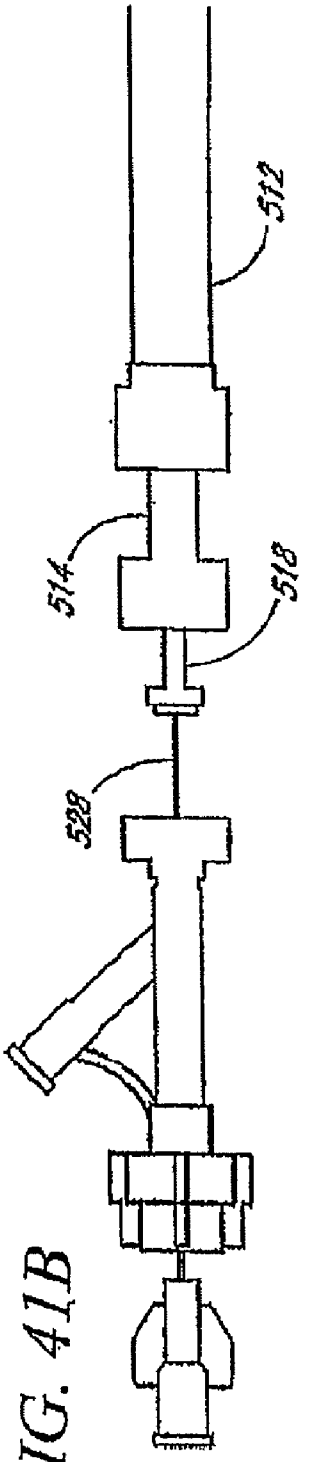

FIG. 41B

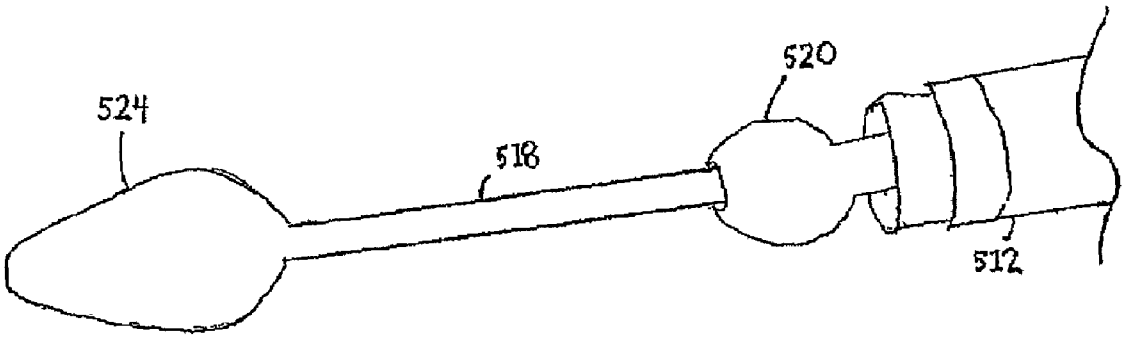

FIG. 42

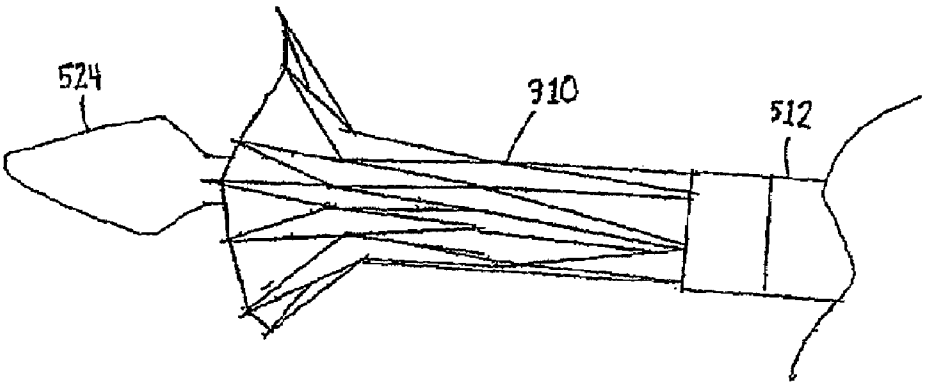

FIG. 43

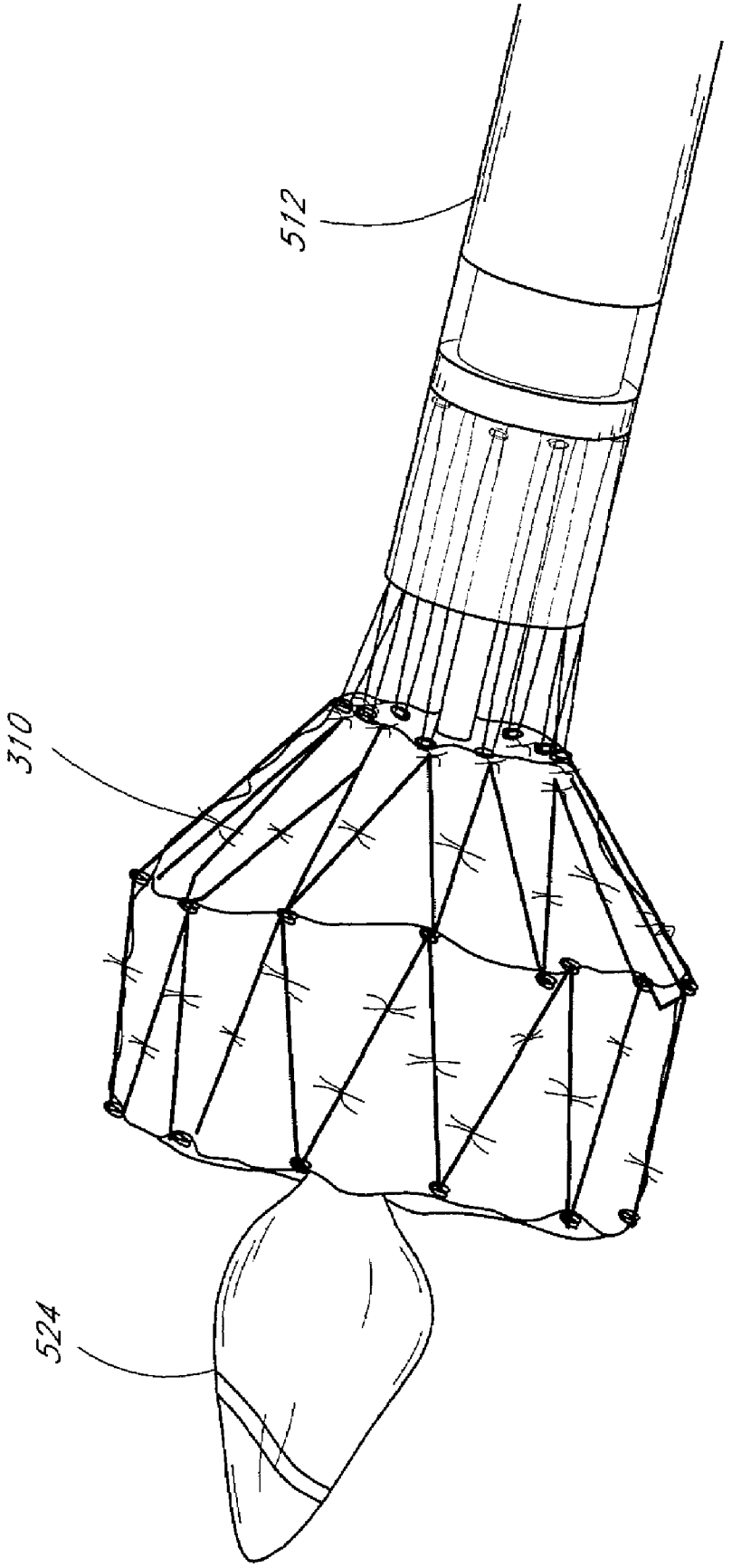

FIG. 44

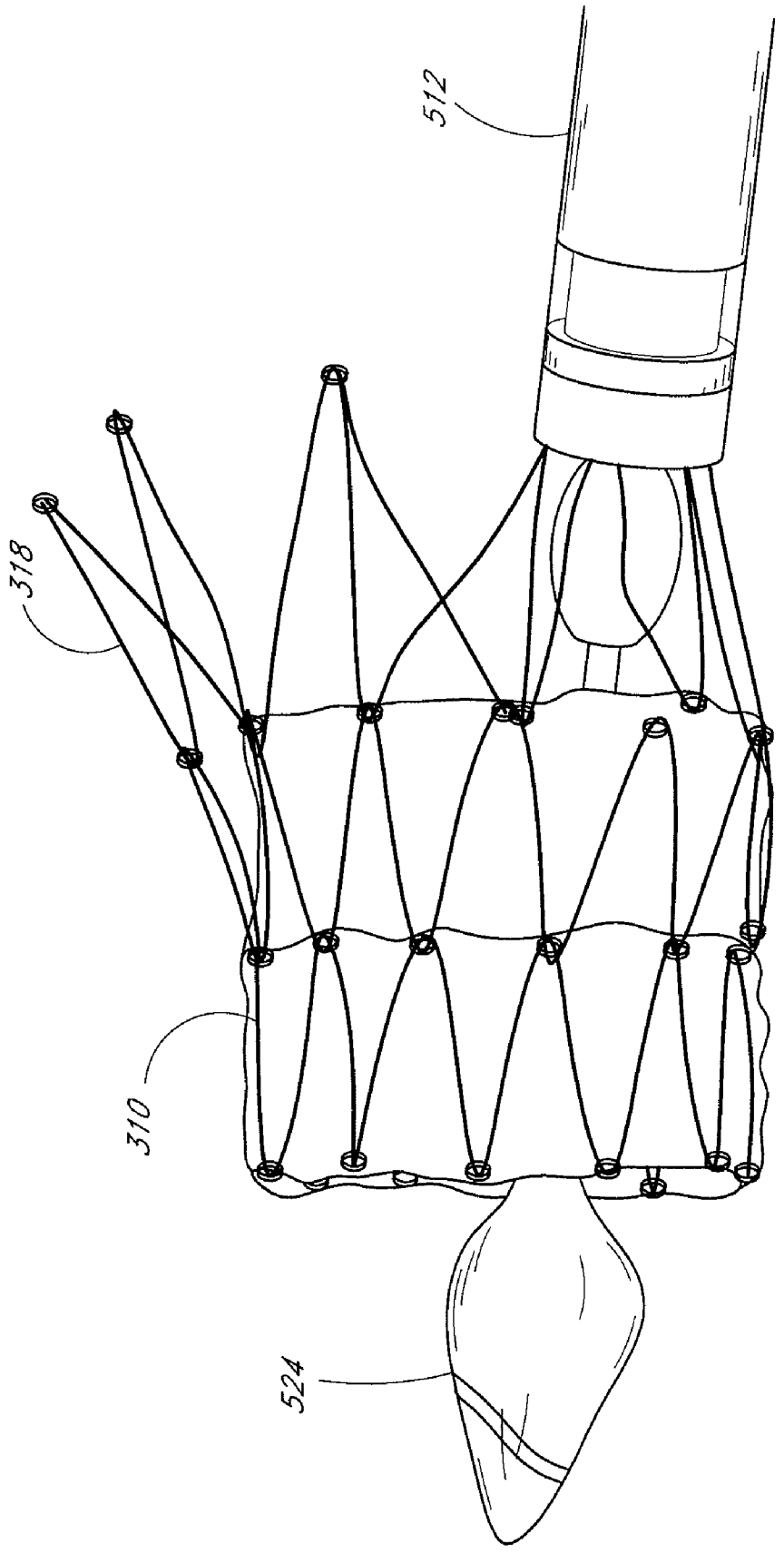

FIG. 45

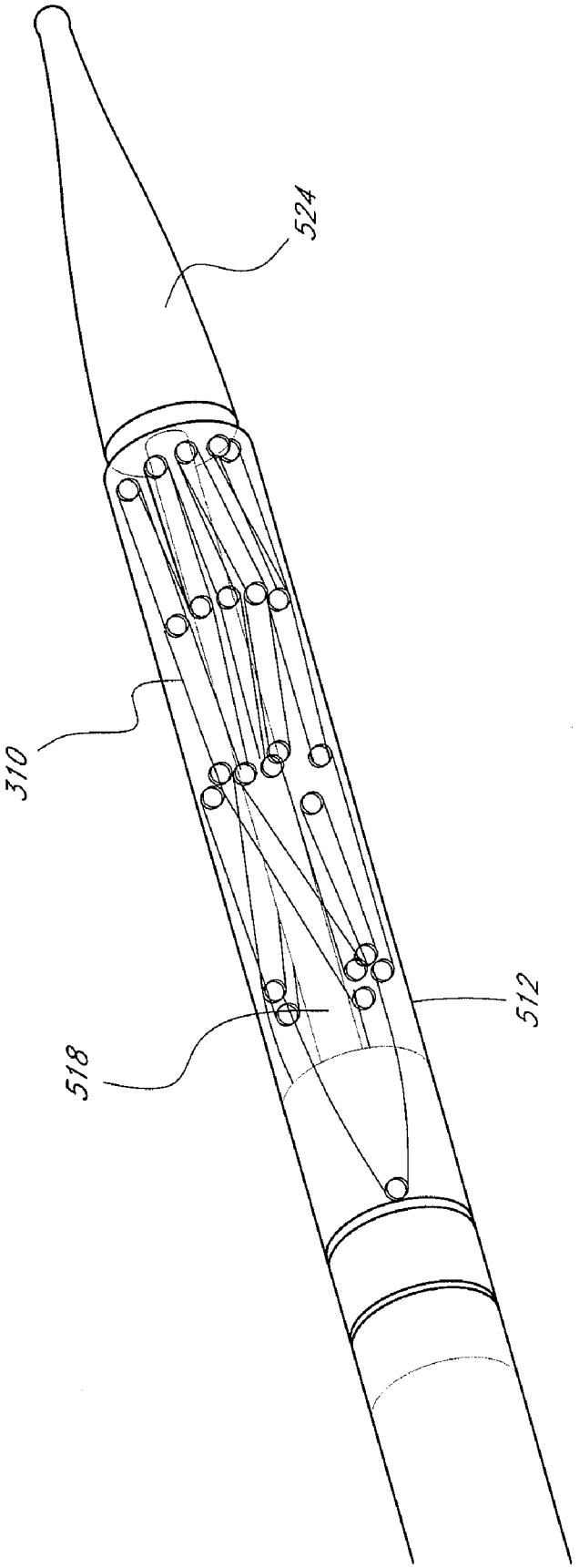

FIG. 46

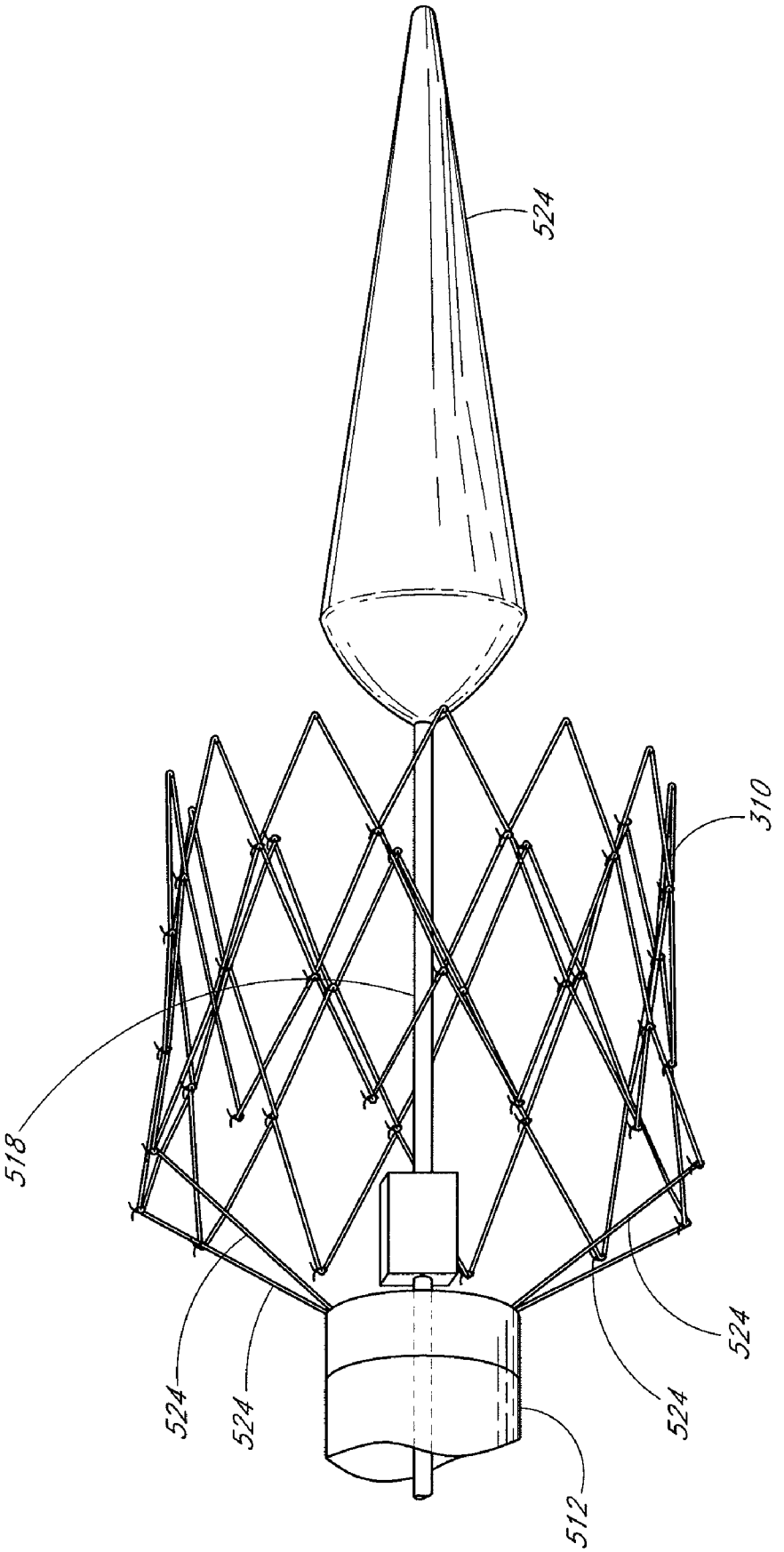

FIG. 47

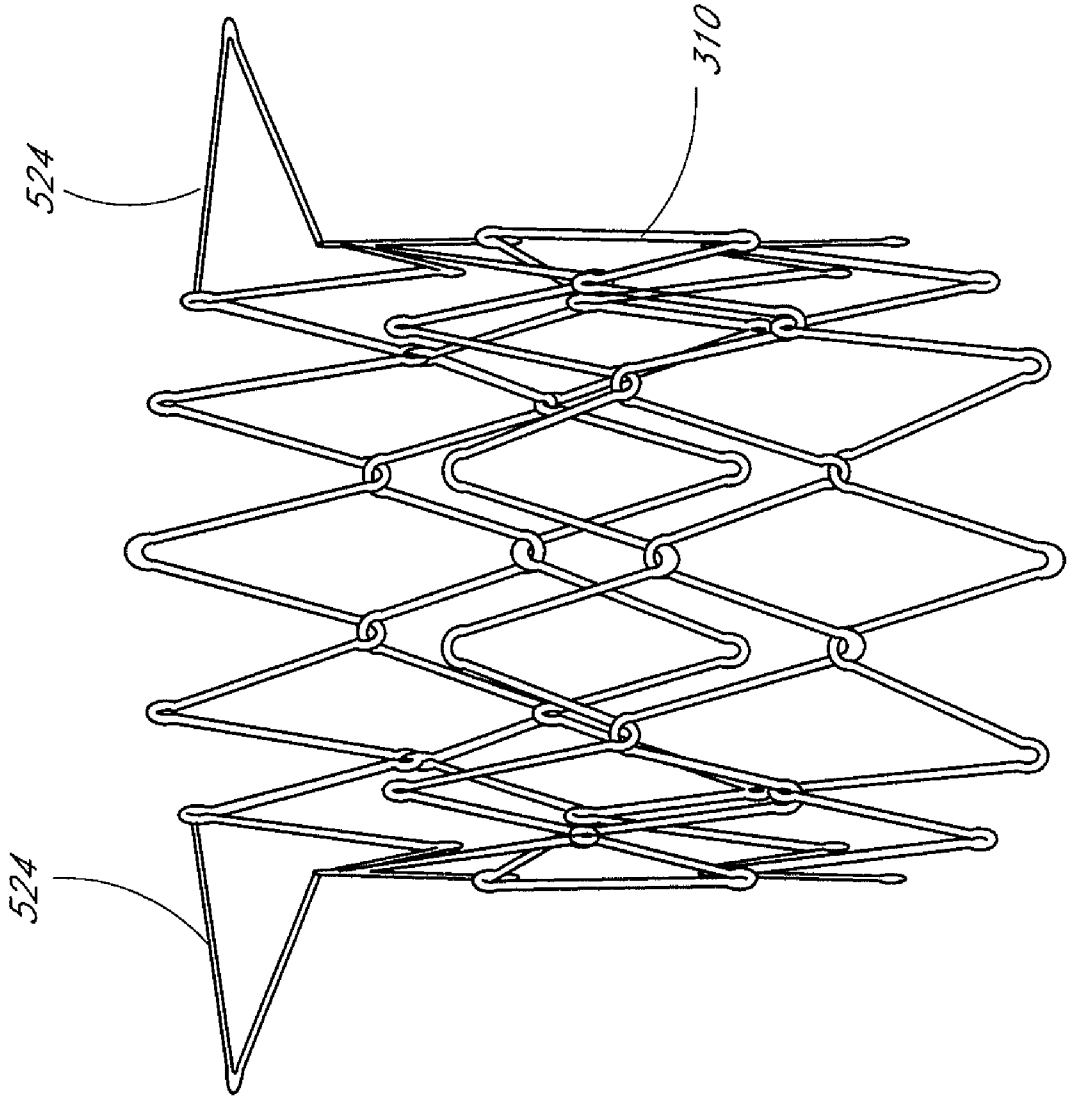

FIG. 48

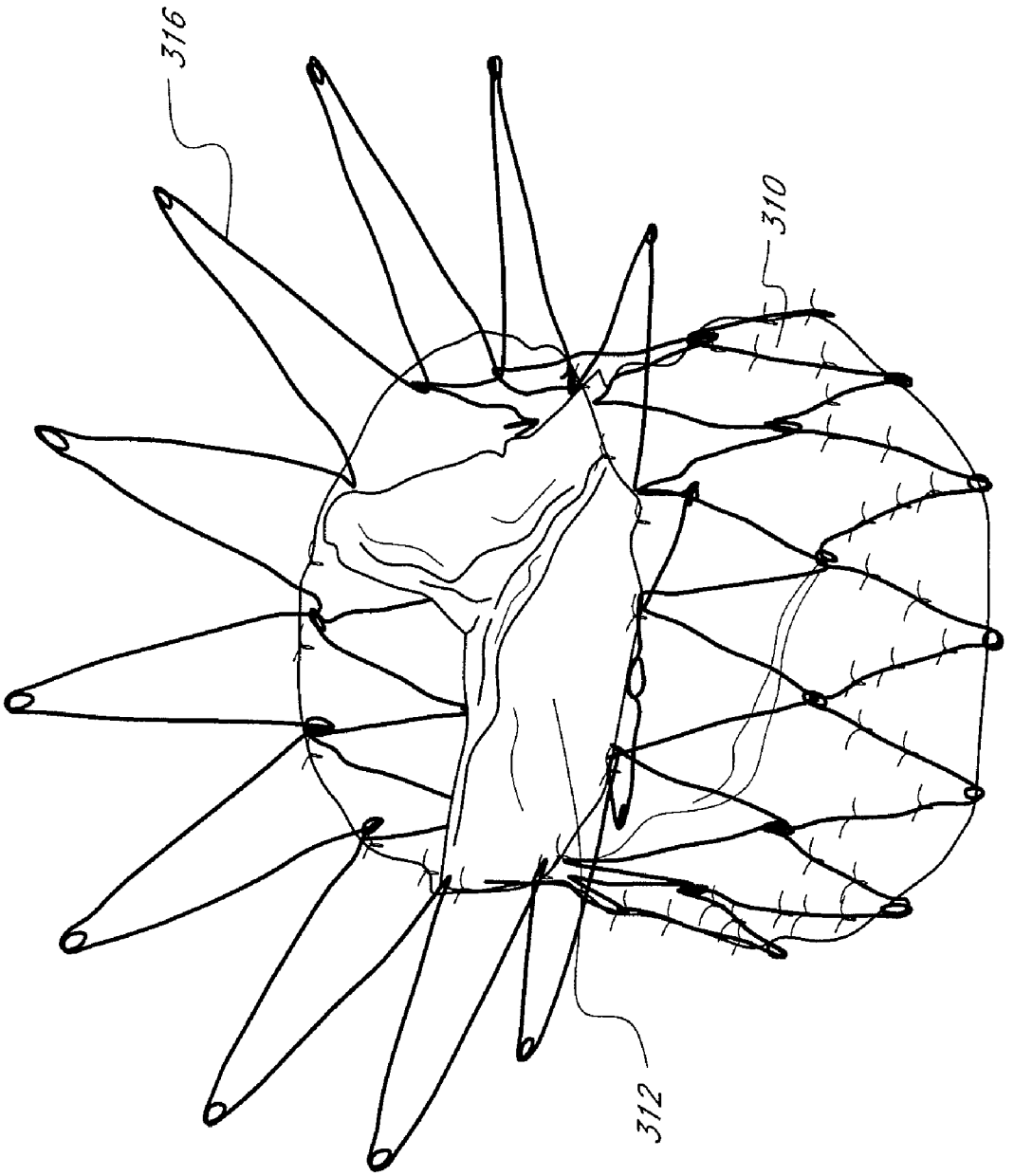

FIG. 49

PROSTHETIC VALVE FOR TRANSLUMINAL DELIVERY

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims priority under 35 U.S.C. §120 as a continuation of U.S. application Ser. No. 12/029,031, filed Feb. 11, 2008, which is a continuation of U.S. application Ser. No. 11/352,614 filed Feb. 13, 2006, now U.S. Pat. No. 7,329,278, which is a continuation of U.S. application Ser. No. 10/412,634 filed Apr. 10, 2003, now U.S. Pat. No. 7,018,406, which is a continuation-in-part of U.S. application Ser. No. 10/130,355, now U.S. Pat. No. 6,830,584, which has a 371(c) date of Nov. 26, 2002 and is the U.S. national phase under §371 of International Application No. PCT/FR00/03176, filed on Nov. 15, 2000, which was published in a language other than English and which claims priority from French Application No. 99/14462 filed on Nov. 17, 1999, now French Patent No. 2,800,984; application Ser. No. 10/412,634is also a continuation-in-part of International Application No. PCT/FR01/03258 filed on Oct. 19, 2001, which was published in a language other than English and which claims priority from French Application No. 00/14028 filed on Oct. 31, 2000, now French Patent No. 2,815,844. The present application also claims priority under 35 U.S.C. §120 as a continuation of U.S. application Ser. No. 11/434,506 filed May 15, 2006,which is a continuation-in-part of U.S. application Ser. No. 10/772,101 filed Feb. 4, 2004, which is a continuation-in-part of U.S. application Ser. No. 10/412,634 filed Apr. 10, 2003, now U.S. Pat. No. 7,018,406, which is a continuation-in-part of U.S. application Ser. No. 10/130,355, now U.S. Pat. No. 6,830,584, which has a 371(c) date of Nov. 26, 2002 and is the U.S. national phase under §371 of International Application No. PCT/FR00/03176, filed on Nov. 15, 2000, which was published in a language other than English and which claims priority from French Application No. 99/14462 filed on Nov. 17, 1999, now French Patent No. 2,800,984; application Ser. No. 10/412,634 is also a continuation-in-part of International Application No. PCT/FR01/03258 filed on Oct. 19, 2001, which was published in a language other than English and which claims priority from French Application No. 00/14028 filed Oct. 31, 2000, now French Patent No. 2,815,844.

FIELD OF THE INVENTION

The present invention relates to a prosthetic cardiac valve and related deployment system that can be delivered percutaneously through the vasculature, and a method for delivering same.

BACKGROUND OF THE INVENTION

Currently, the replacement of a deficient cardiac valve is often performed by opening the thorax, placing the patient under extracorporeal circulation, temporarily stopping the heart, surgically opening the heart, excising the deficient valve, and then implanting a prosthetic valve in its place. U.S. Pat. No. 4,106,129 to Carpentier describes a bioprosthetic heart valve with compliant orifice ring for surgical implantation. This procedure generally requires prolonged patient hospitalization, as well as extensive and often painful recovery. It also presents advanced complexities and significant costs.

To address the risks associated with open heart implantation, devices and methods for replacing a cardiac valve by a less invasive means have been contemplated. For example, French Patent Application No. 99 14462 illustrates a technique and a device for the ablation of a deficient heart valve by percutaneous route, with a peripheral valvular approach. International Application (PCT) Nos. WO 93/01768 and WO 97/28807, as well as U.S. Pat. Nos. 5,814,097 to Sterman et al., U.S. Pat. No. 5,370,685 to Stevens, and U.S. Pat. No. 5,545,214 to Stevens illustrate techniques that are not very invasive as well as instruments for implementation of these techniques.

U.S. Pat. No. 3,671,979 to Moulopoulos and U.S. Pat. No. 4,056,854 to Boretos describe a catheter mounted artificial heart valve for implantation in close proximity to a defective heart valve. Both of these prostheses are temporary in nature and require continued connection to the catheter for subsequent repositioning or removal of the valve prosthesis, or for subsequent valve activation.

With regard to the positioning of a replacement heart valve, attaching this valve on a support with a structure in the form of a wire or network of wires, currently called a stent, has been proposed. This stent support can be contracted radially in such a way that it can be introduced into the body of the patient percutaneously by means of a catheter, and it can be deployed so as to be radially expanded once it is positioned at the desired target site. U.S. Pat. No. 3,657,744 to Ersek discloses a cylindrical, stent-supported, tri-leaflet, tissue, heart valve that can be delivered through a portion of the vasculature using an elongate tool. The stent is mounted onto the expansion tool prior to delivery to the target location where the stent and valve is expanded into place. More recently, U.S. Pat. No. 5,411,552 to Andersen also illustrates a technique of this type. In the Andersen patent, a stent-supported tissue valve is deliverable percutaneously to the native heart valve site for deployment using a balloon or other expanding device. Efforts have been made to develop a stent supported valve that is self-expandable, using memory materials such as Nitinol.

The stent supported systems designed for the positioning of a heart valve introduce uncertainties of varying degree with regard to minimizing migration from the target valve site. A cardiac valve that is not adequately anchored in place to resist the forces of the constantly changing vessel wall diameter, and turbulent blood flow therethrough, may dislodge itself, or otherwise become ineffective. In particular, the known stents do not appear to be suited to sites in which the cardiac wall widens on either proximally and/or distally of the valve annulus situs. Furthermore, the native cardiac ring remaining after ablation of the native valve can hinder the positioning of these stents. These known systems also in certain cases create problems related to the sealing quality of the replacement valve. In effect, the existing cardiac ring can have a surface that is to varying degrees irregular and calcified, which not only lessens the quality of the support of the stent against this ring but also acts as the source of leaks between the valve and this ring. Also, these systems can no longer be moved at all after deployment of the support, even if their position is not optimal.

Also, the existing techniques are, however, considered not completely satisfactory and capable of being improved. In particular, some of these techniques have the problem of involving, in any case, putting the patient under extracorporeal circulation and temporarily stopping of the heart; they are difficult to put into practice; they do not allow precise control of the diameter according to which the natural valve is cut, in view of the later calibration of the prosthetic valve; they lead to risks of diffusion of natural valve fragments, often calcified, into the organism, which can lead to an embolism, as

well as to risks of perforation of the aortic or cardiac wall; they, moreover, induce risks of acute reflux of blood during ablation of the natural valve and risks of obstruction of blood flow during implantation of the device with a balloon expandable stent for example.

SUMMARY OF THE INVENTION

The object of the present invention is to transluminally provide a prosthetic valve assembly that includes features for preventing substantial migration of the prosthetic valve assembly once delivered to a desired location within a body. The present invention aims to remedy these significant problems. Another objective of the invention is to provide a support at the time of positioning of the replacement valve that makes it possible to eliminate the problem caused by the native valve sheets, which are naturally calcified, thickened and indurated, or by the residues of the valve sheets after valve resection. Yet another objective of the invention is to provide a support making possible complete sealing of the replacement valve, even in case of an existing cardiac ring which has a surface which is to varying degrees irregular and/or to varying degrees calcified. Another objective of the invention is to have a device that can adapt itself to the local anatomy (i.e. varying diameters of the ring, the subannular zone, the sino-tubular junction) and maintain a known diameter of the valve prosthesis to optimize function and durability. The invention also has the objective of providing a support whose position can be adapted and/or corrected if necessary at the time of implantation.

The present invention is a prosthesis comprising a tissue valve supported on a self-expandable stent in the form of a wire or a plurality of wires that can be contracted radially in order to make possible the introduction of the support-valve assembly into the body of the patient by means of a catheter, and which can be deployed in order to allow this structure to engage the wall of the site where the valve is to be deployed. In one embodiment, the valve is supported entirely within a central, self-expandable, band. The prosthetic valve assembly also includes proximal and distal anchors. In one embodiment, the anchors comprise discrete self-expandable bands connected to the central band so that the entire assembly expands in unison into place to conform more naturally to the anatomy. The valve can be made from a biological material, such as an animal or human valve or tissue, or from a synthetic material, such as a polymer, and includes an annulus, leaflets, and commissure points. The valve is attached to the valve support band with, for example, a suture. The suture can be a biologically compatible thread, plastic, metal, or adhesive, such as cyanoacrylate.

In one embodiment, the valve support band is made from a single wire bent in a zigzag manner to form a cylinder. Alternatively, the valve support band can be made from a plurality of wires interwoven with one another. The wire can be made from stainless steel, silver, tantalum, gold, titanium, or any suitable tissue or biologically compatible plastic, such as ePTFE or Teflon. The valve support band may have a loop at its ends so that the valve support band can be attached to an upper anchor band at its upper end, and a lower anchor band at its lower end. The link can be made from, for example, stainless steel, silver, tantalum, gold, titanium, any suitable plastic material, or suture.

The prosthetic valve assembly is compressible about its center axis such that its diameter can be decreased from an expanded position to a compressed position. The prosthetic valve assembly may be loaded onto a catheter in its compressed position, and so held in place. Once loaded onto the catheter and secured in the compressed position, the prosthetic valve assembly can be transluminally delivered to a desired location within a body, such as a deficient valve within the heart. Once properly positioned within the body, the catheter can be manipulated to release the prosthetic valve assembly and expand it into its expanded position. In one embodiment, the catheter includes adjustment hooks such that the prosthetic valve assembly may be partially released and expanded within the body and moved or otherwise adjusted to a final desired location. At the final desired location, the prosthetic valve assembly may be totally released from the catheter and expanded to its full expanded position. Once the prosthetic valve assembly is totally released from the catheter and expanded, the catheter may be removed from the body.

Other embodiments are contemplated. In one such alternative embodiment, this structure comprises an axial valve support portion, which has a structure in the form of a wire or in the form of a network of wires suitable for receiving the replacement valve mounted on it, and suitable for supporting the cardiac ring remaining after the removal of the deficient native valve; at least one axial wedging portion, which has a structure in the form of a wire or in the form of a network of wires that is distinct from the structure of said axial valve support portion, and of which at least a part has, when deployed a diameter greater or smaller than that of said deployed axial valve support portion, such that this axial wedging portion is suitable for supporting the wall bordering said existing cardiac ring; and at least a wire for connecting said portions, this wire or these wires being connected at points to these portions in such a way as not to obstruct the deployment of said axial portions according to their respective diameters. The embodiment thus provides a support in the form of at least two axial portions that are individualized with respect to one another with regard to their structure, which are connected in a localized manner by at least one wire; where this wire or these wires do not obstruct the variable deployment of the axial portion with the valve and of the axial wedging portion(s).

The presence of a structure in the form of a wire or in the form of a network of wires in the axial valve support portion makes possible a perfect assembly of this valve with this structure, and the shape as well as the diameter of this axial portion can be adapted for supporting the existing cardiac ring under the best conditions. In particular, this axial valve support portion can have a radial force of expansion such that it pushes back ("impacts") the valve sheets that are naturally calcified or the residues of the valve sheets after valve resection onto or into the underlying tissues, so that these elements do not constitute a hindrance to the positioning of the replacement valve. This structure also makes it possible to support possible anchoring means for the support and/or possible sealing means for the space existing between the existing cardiac ring and the replacement valve, as indicated below.

The form and/or diameter of each axial wedging portion can be adapted for supporting the cardiac wall situated at the approach to the existing cardiac ring under the best conditions. In particular, this axial wedging portion can have a tubular shape with a constant diameter greater than that of the axial valve support portion, or the form of a truncated cone whose diameter increases with distance from the axial valve support portion.

Preferably, the tubular support has an axial valve support portion in the form of at least two parts, of which at least one is suitable for supporting the valve and of which at least another is suitable for pushing back the native valve sheets or the residues of the native valve sheets after valve resection,

into or onto the adjacent tissue in order to make this region able to receive the tubular support. This axial valve support portion eliminates the problem generated by these valve or cardiac ring elements at the time of positioning of the replacement valve. The radial force of this axial valve support portion, by impacting all or part of the valvular tissue or in the wall or its vicinity in effect ensures a more regular surface more capable of receiving the valve support axis. It also ensures a better connection with the wall while reducing the risk of peri-prosthetic leakage. Furthermore, such a structure permits the valve to maintain a diameter within a preset range to ensure substantial coaptivity and avoid significant leakage.

Specifically, in order to support the valve, the axial valve support portion can have a part in the form of an undulating wire with large-amplitude undulations, and a part in the form of an undulating wire with small-amplitude undulations, adjacent to said part with large amplitude undulations, having a relatively great radial force in order to make it possible to push said valvular tissue against or into the wall of the passage. Preferably, the support according to one embodiment of the present invention has two axial wedging portions, one connected to an axial end of said valve support portion and the other to the other axial end of this same valve support portion. These two axial wedging portions thus make it possible to wedge the support on both sides of the existing cardiac ring, and consequently make possible complete wedging of the support in two opposite directions with respect to the treated site. If necessary, for example, in the case in which the passage with the valve has an aneurysm, the support according to the invention has: an axial holding portion, suitable for supporting in the deployed state the wall of the passage, and connecting wires such as the aforementioned connecting wires, connecting said axial valve support portion and said axial holding portion, these wires having a length such that the axial holding portion is situated after implantation a distance away from the axial valve support portion. This distance allows said axial holding portion to rest against a region of the wall of the passage not related to a possible defect which may be present at the approach to the valve, particularly an aneurysm. The length of the connecting wires can also be calculated in order to prevent the axial holding portion from coming into contact with the ostia of the coronary arteries. The aforementioned axial portions (valve support, wedging, holding portions) can have a structure in the form of an undulating wire, in zigzag form, or preferably a structure in diamond-shaped mesh form, the mesh parts being juxtaposed in the direction of the circumference of these portions. This last structure allows a suitable radial force making it possible to ensure complete resting of said portions against the wall which receives them.

The support according to the invention can be produced from a metal that can be plastically deformed. The instrument for positioning of the support then includes a balloon which has an axial portion with a predetermined diameter, adapted for realizing the deployment of said axial valve support portion, and at least one axial portion shaped so as to have, in the inflated state, a greater cross section than that of the passage to be treated, in such a way as to produce the expansion of the axial wedging portion placed on it until this axial wedging portion encounters the wall which it is intended to engage. The support according to this embodiment of the present invention can also be produced from a material that can be elastically deformed or even a material with shape memory, such as the nickel-titanium alloy of the type known as "Nitinol," which can be contracted radially at a temperature different from that of the body of the patient and which regains its original shape when its temperature approaches or reaches that of the body of the patient.

According to another possibility, the support is produced from a material with shape memory but that can be plastically deformed, or has parts made from a material with shape memory and parts made from a material that can be plastically deformed, and is formed in such a way that it can be brought, by shape memory or plastic deformation, from a state of contraction to a stable intermediate state of deployment between the state of contraction and the state of total deployment, and then by plastic deformation or shape memory respectively, from said intermediate state of deployment to said state of total deployment; in said intermediate state of deployment, the support has dimensions such that it remains mobile with respect to the site to be treated. The support is thus brought to the site to be treated and then is deployed from its intermediate state; its position can then possibly be adapted and/or corrected, and then the support is brought to its state of total deployment. Specifically, the aforementioned material may have shape memory but that can be plastically deformed, such as a nickel-titanium alloy of the type called "martensitic Nitinol" that can undergo plastic deformation by means of a balloon.

Advantageously, the support according to the invention has some anchoring means suitable for insertion into the wall of the site to be treated, and is shaped in such a way as to be mobile between an inactive position, in which it does not obstruct the introduction of the support into the body of the patient, and an active position, in which it is inserted into the wall of the site to be treated. Substantially complete immobilization of the support at the site is thus obtained. In particular, this anchoring means can be in the form of needles and can be mounted on the support between retracted positions and radially projected positions. Advantageously, the axial valve support portion has, at the site of its exterior surface, a sealing means shaped in such a way as to absorb the surface irregularities that might exist at or near the existing cardiac ring. This sealing means can consist of a peripheral shell made from a compressible material such as polyester or tissue identical to the valve or a peripheral shell delimiting a chamber and having a radially expandable structure, this chamber being capable of receiving an inflating fluid suitable for solidifying after a predetermined delay following the introduction into said chamber. This sealing means can also include a material that can be applied between the existing cardiac ring and the axial valve support portion, this material being capable of solidifying after a predetermined delay following this application. Specifically, in this case, this material is capable of heat activation, for example, by means of a laser, through the balloon, or capable of activation by emission of light of predetermined frequency, for example, by means of an ultraviolet laser, through the balloon. Said sealing means can also be present in the form of an inflatable insert with a spool-shaped cross section in the inflated state, which can be inserted between the existing cardiac ring and the axial valve support portion, Said spool shape allows this insert to conform to the best extent possible to the adjacent irregular structures and to provide a better seal.

An assembly and method for removing the native valve is also contemplated. In particular, the invention has the objective of providing a device which gives complete satisfaction with regard to the exeresis and replacement of the valve, while allowing one to operate without opening of the thorax, stopping of the heart and/or opening of the heart, and preventing any diffusion into the circulatory system of fragments of the removed valve. In one embodiment, the device comprises: an elongated support element; a first series of elongated blades

arranged around the circumference of said elongated element; these blades are connected in a pivoting manner to the elongated element at the site of their proximal longitudinal ends and each has a sharp edge at the site of its distal longitudinal end; these blades can pivot with respect to the elongated element between a folded up position, in which they are near the wall of the elongated element in such a way that they do not stand in the way of the introduction and sliding of the device in the body channel in which the valve is located, in particular in the aorta, and an opened out position, in which these blades are spread out in the form of a corolla in such a way that their sharp edges are placed in extension of one another and thus constitute a sharp circular edge; a second series of blades, arranged consecutively to said first series of blades in the distal direction; the blades of this second series of blades have a structure identical to that of the blades of said first series of blades, except that these blades of this second series are connected to the elongated element by their distal longitudinal ends and each has a sharp edge at the site of its proximal longitudinal end; means making it possible to bring the blades of said first and second series of blades from their folded up position to their opened out position; means making it possible to move said series of blades axially in the direction of one another, between a position of mutual distancing of these series of blades, in which one series of blades can be placed axially on one side of the natural valve while the other series of blades is placed axially on the other side of this valve, and a close together position, in which the sharp circular edges of these two series of blades are brought in mutual contact and thus cut off the natural valve, making it possible to position each of the two aforementioned series of blades on one side of this valve.

The device according to the invention can be introduced percutaneously into said body channel and can be slid in this channel until each of the aforementioned series of blades is placed on one side of the valve. This position is identified using said means of identification. A system of peripheral perfusion or extracorporeal circulation or a blood pump through the center of the delivery system pumping blood from the left ventricle (proximal to the aortic valve) to the aorta (distal to the aortic valve) can be put in place in order to facilitate the flow of the blood, for the purpose of preventing stagnation of the blood in the heart. After the aforementioned positioning of the device, the blades of the two series of blades are spread out; then these two series are brought closer together until the valve is cut off. The configuration of these blades makes it possible to execute this cutting in a single operation, therefore without generating fragments which can be diffused into the circulatory system, or at the very least generating only very few such fragments; this configuration moreover makes possible precise control of the diameter according to which the natural valve is cut, in view of later calibration of the prosthetic valve. The blades are then brought back to the folded up position. The prosthetic valve is then put in place.

This valve can be separate from the device, in which case the latter is removed and then the prosthetic valve is introduced and positioned in said body channel by means of a separate device. Preferably however, the device according to the invention includes a proximal prosthetic valve, with a structure which can be spread out radially, with it possible for this prosthetic valve to occupy a folded up position, in which it is near the wall of said elongated element and does not sand in the way of the introduction and siding of the device in said body channel, and an opened out position, in which it rests against the wall of this channel and is capable of replacing the natural cardiac valve.

The device thus makes it possible to introduce and to position the prosthetic valve at the appropriate place in the body channel, by the same action as that making it possible to cut off the natural valve. After cutting off of the latter, the device is slid axially in the distal direction in order to bring the prosthetic valve to the appropriate site in this channel, after which this prosthetic valve is spread out. The device is then withdrawn, and the cut off natural valve is recovered.

Preferably, said elongated support element is a tubular catheter. This catheter thus allows the blood to flow through it during the exeresis of the natural valve. The cross section of the channel of this catheter can be sufficient to allow the blood to flow through this channel with or without the help of a pump, which limits or prevents resorting to putting the patient in extracorporeal circulation. The catheter can also have a small diameter, which facilitates the introduction and sliding of the device in the body channel, but it is then necessary to provide peripheral circulation by an external assistance system such as an extracorporeal circulation system. The catheter has a lateral distal opening in order to allow the blood to rejoin the body channel, for example, the ascending aorta, this opening being arranged in such a way that the length of catheter passed through the blood is as short as possible.

Preferably, the device has a distal inflatable balloon, placed at the site of the exterior surface of said elongated element; this balloon is configured so as to occupy a folded up position, in which it has a cross section such that it does not stand in the way of the introduction and to the sliding of the device in said body channel, and an opened out position, in which it occupies he whole space existing between the exterior surface of said elongated element and the wall of said body channel and rests, by a peripheral edge which it has, against this wall. The balloon is inflated after the positioning of the series of blades on both sides of the natural valve, in order to prevent reflux of the blood during the ablation of the natural valve. If said elongated element is a catheter, this balloon moreover makes it possible to case this blood to flow only through the catheter. Once the prosthetic valve is positioned, the balloon is brought back to a folded up position so as to re-establish the blood flow through the body channel.

Preferably, the device has a distal filter made of flexible material, placed in the site of the exterior surface of said elongated element; this filter is configured so that it can occupy a folded up position, in which it has a cross section such that it does not stand in the way of the introduction and sliding of the device in said body channel, and an opened out position, in which it occupies the whole space existing between the exterior surface of said elongated element and the wall of the channel and rests, by a peripheral edge which it has, against this wall. This filter makes it possible to catch possible fragments generated by the exeresis of the valve and to retain them so that they are removed from the blood circulation. The device can have some means making it possible to move said series of blades in the axial direction independently from said balloon and/or from said filter. Once opened out, this or these means do not have to be moved axially in the body channel during the aforementioned axial movement of the series of blades.

Said balloon and/or said filter can also be separate from the device, being mounted on an elongated support element which belongs to them. In case of operation on a mitral valve, this balloon and/or this filter is/are introduced into the aorta by a peripheral artery route, and the device is itself introduced into the heart by the peripheral venous system, up to the right atrium and then into the left atrium through the interatrial septum, up to the site of the mitral valve. The prosthetic valve can advantageously have a frame made of a material with a

shape memory, particularly a nickel-titanium alloy known as "Nitinol." This same valve can have valves made of biological material (preserved animal or human valves) or valves made of synthetic material such as a polymer. When replacing an aortic valve the device may be alternatively introduced in a retrograde manner through a peripheral artery (femoral artery) or through a venous approach and trans-septally (antegrade).

The above embodiments and methods of use are explained in more detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross-sectional side view of one embodiment of an assembly of the present invention for removing and replacing a native heart valve percutaneously;

FIG. **2** is a cross-section axial view of the assembly of FIG. **1** taken at line II-II, shown in a closed condition;

FIG. **3** is a cross-section axial view of the assembly of FIG. **1** taken at line II-II, shown in an opened condition;

FIG. **4** is a perspective schematic view of one embodiment of a prosthetic valve of the present invention;

FIGS. **5** to **9** are schematic views of the assembly of the present invention positioned in a heart, at the site of the valve that is to be treated, during the various successive operations by means of which this valve is cut out and the prosthetic valve shown in FIG. **4** deployed;

FIG. **10** is a schematic view of the prosthetic valve shown of FIG. **4** shown in a deployed state;

FIG. **11** is a schematic view of an alternative embodiment of the assembly of the present invention shown treating a mitral valve;

FIG. **12** is a cross-sectional view of a section of a blade used in excising the native valve;

FIG. **13** is a schematic view of one embodiment of the support structure of the prosthesis assembly of the present invention;

FIG. **14** is a cross-sectional view of the support of FIG. **13** showing a heart valve supported by the central portion of the support;

FIG. **15** is an end view of the support of FIGS. **13** and **14** in the deployed state;

FIG. **16** is an end view of the support of FIGS. **13** and **14** in the contracted state;

FIG. **17** is a schematic view of a heart with an embodiment of the present inventive prosthesis shown deployed in place;

FIG. **18** is a schematic view of an alternative embodiment of the present invention;

FIG. **19** is schematic view of an alternative embodiment of the present invention;

FIG. **20** is a detail view of a part of the support structure of one embodiment of the present invention;

FIG. **21** is a schematic view of the support of FIG. **19** shown in a deployed state;

FIG. **22** is schematic view of an alternative embodiment of the present invention;

FIG. **23** is a detail view of the support of FIG. **22** shown in the contracted state;

FIG. **24** is a detail view of the support of FIG. **23** taken along line **23-23**;

FIG. **25** is a detail view of the support of FIG. **22** shown in the expanded state;

FIG. **26** is a detail view of the support of FIG. **25** taken along line **25-25**;

FIG. **27** is a schematic view of an alternative embodiment of the present invention;

FIG. **28** is a detailed cross section view of the support of FIG. **27**;

FIG. **29** is a partial schematic view in longitudinal section of the support of the present invention and of a calcified cardiac ring;

FIG. **30** is a schematic view of an alternative to the support of FIG. **29**;

FIG. **31** is a schematic view of an alternative to the support of FIG. **29**;

FIGS. **32** and **33** are schematic views of an alternative to the support of FIG. **29**;

FIG. **34** is a schematic cross-sectional view of a balloon corresponding to the support structure of FIGS. **19** to **21**;

FIG. **35** is a schematic longitudinal sectional view of an alternative embodiment of the balloon of FIG. **34**;

FIG. **36** is a schematic view of a heart with an embodiment of the present inventive prosthesis shown deployed in place;

FIG. **37** is a perspective view of one embodiment of a prosthetic valve assembly of the present invention;

FIG. **38** is a side view of the prosthetic valve assembly of FIG. **37**;

FIG. **39** is a photograph of one embodiment of the prosthetic valve assembly of FIG. **37**;

FIG. **40** is a photograph of an alternative embodiment of the prosthetic valve assembly with a sheath around the valve;

FIG. **41**A is a perspective view of a distal portion of a catheter assembly for use in deploying the prosthetic valve assembly described herein;

FIG. **41**B is a perspective view of a proximal portion of the catheter assembly of FIG. **41**A;

FIG. **42** is a photograph of the distal portion of the catheter assembly of FIG. **41**A;

FIGS. **43** through **45** are photographs of the catheter assembly of FIG. **40**A showing deployment of a prosthesis assembly in sequence;

FIGS. **46** and **47** are photographs of the catheter assembly of FIG. **41**A showing deployment of an alternative prosthesis assembly;

FIG. **48** is a photograph of the alternative prosthesis assembly shown in FIGS. **46** and **47**.

FIG. **49** is a photograph of an alternative embodiment of the prosthetic valve assembly of FIG. **37** showing only a distal anchor;

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Reference is now made to the figures wherein like parts are designated with like numerals throughout. FIGS. **1** to **3** represent a device **1** for replacing a heart valve by a percutaneous route. This device comprises a tubular catheter **2** formed from three tubes **5**, **6**, **7** engaged one inside the other and on which there are placed, from the proximal end to the distal end (considered with respect to the flow of blood, that is to say from right to left in FIG. **1**), a prosthetic valve **10**, two series of blades **11**, **12**, a balloon **13** and a filter **14**. The three tubes **5**, **6**, **7** are mounted so that they can slide one inside the other. The interior tube **5** delimits a passage **15**, the cross section of which is large enough to allow blood to flow through it. At the proximal end, the intermediate tube **6** forms a bell housing **6***a* delimiting, with the interior tube **5**, an annular cavity **17** in which the prosthetic valve **10** is contained in the furled condition.

FIG. **4** shows that this valve **10** comprises an armature **20** and valve leaflets **21** mounted so that they are functionally mobile on this armature **20**. The armature consists of a collection of wires **22**, **23**, **24** made of shape memory material,

particularly of nickel-titanium alloy known by the name of "NITINOL;" namely, (i) a proximal end wire **22** which, when the valve **10** is in the deployed state, has a roughly circular shape; (ii) a distal end wire **23** forming three corrugations in the axial direction, these corrugations being distributed uniformly around the circumference of the valve **10**, and (iii) an intermediate wire **24** forming longitudinal corrugations between the wires **22** and **23**, this wire **24** being connected to the latter ones via the ends of each of these corrugations. The valve leaflets **21** for their part are made of biological material (preserved human or animal valve leaflets) or of synthetic material, such as a polymer. The armature **20** may, when its material is cooled, be radially contracted so that the valve **10** can enter the cavity **17**. When this material is heated to body temperature, this armature **20** returns to its original shape, depicted in FIG. **4**, in which it has a diameter matched to that of a bodily vessel, particularly the aorta, in which the native valve that is to be treated lies. This diameter of the armature **20** is such that the valve **10** bears against the wall of the bodily vessel and is immobilized in the axial direction with respect to that vessel.

Each series of blades **11**, **12** comprises metal elongate blades **30** and an inflatable balloon **31** situated between the catheter **2** and these blades **30**. The blades **30** have a curved profile and are arranged on the circumference of the catheter **2**, as shown in FIGS. **2** and **3**. The blades **30** of the proximal series **11** are connected pivotably to the tube **6** by their proximal ends and comprise a cutting distal edge **30***a*, while the blades **30** of the distal series **12** are connected pivotably to the exterior tube **7** by their distal ends and comprise a cutting proximal edge **30***b*. The connection between the blades **30** and the respective tubes **6** and **7** is achieved by welding the ends of the blades **30** together to form a ring, this ring being fixed axially to the corresponding tube **6**, **7** by crimping this ring onto this tube **6**, **7**, the pivoting of the blades **30** being achieved by simple elastic deformation of these blades **30**. This pivoting can take place between a position in which the blades **30** are furled, radially internally with respect to the catheter **2** and shown in FIGS. **1** and **2**, and a position in which these blades **30** are unfurled, radially externally with respect to this catheter **2** and shown in FIG. **3**. In the furled position, the blades **30** lie close to the wall of the tube **6** and partially overlap each other so that they do not impede the introduction and the sliding of the device **1** into and in the bodily vessel in which the native valve that is to be treated lies; in said unfurled position, the blades **30** are deployed in a corolla so that their cutting edges **30***a*, **30***b* are placed in the continuation of one another and thus constitute a circular cutting edge visible in FIG. **3**.

Each balloon **31**, placed between the tube **3** and the blades **30**, may be inflated from the end of the catheter **2** which emerges from the patient, via a passage **32** formed in the tube **6**. It thus, when inflated, allows the blades **30** to be brought from their furled position into their unfurled position, and performs the reverse effect when deflated. The axial sliding of the tube **6** with respect to the tube **7** allows the series of blades **11**, **12** to be moved axially toward one another, between a spaced-apart position shown in FIG. **1**, and a close-together position. In the former of these positions, one series of blades **11** may be placed axially on one side of the native valve while the other series of blades **12** is placed axially on the other side of this valve, whereas in the latter of these positions, the circular cutting edges of these two series of blades **11**, **12** are brought into mutual contact and thus cut through the native valve in such a way as to detach it from said bodily vessel. The tubes **5** to **7** further comprise marks (not visible in the figures) in barium sulfate allowing the axial position of the device **1** with respect to the native valve to be identified percutaneously so that each of the two series of blades **11**, **12** can be placed on one axial side of this valve. These tubes **5** to **7** also comprise lateral distal openings (not depicted) to allow the blood to reach the bodily vessel, these openings being formed in such a way that the length of catheter **2** through which the blood flows is as short as possible, that is to say immediately after the filter **14**, in the distal direction.

The balloon **13** is placed on the exterior face of the tube **7**, distally with respect to the series **12**. This balloon **13** has an annular shape and is shaped to be able to occupy a furled position in which it has a cross section such that it does not impede the introduction and sliding of the device **1** into and in said bodily vessel, and an unfurled position, in which it occupies all of the space between the exterior face of the tube **7** and the wall of said bodily vessel and, via a peripheral edge **13***a* which it comprises, bears against this wall.

The filter **14** is placed distally with respect to the balloon **13**, on the tube **7**, to which it is axially fixed. This filter **14** is made of flexible material, for example polyester netting, and is shaped to be able to occupy a furled position in which it has a cross section such that it does not impede the introduction and sliding of the device **1** into and in said bodily vessel, and an unfurled position in which it occupies all of the space between the exterior face of the catheter **2** and the wall of this vessel and, via a peripheral edge **14***a* which it comprises, bears against this wall.

An inflatable balloon **35** is placed between the tube **7** and the filter **14** so as, depending on whether it is inflated or deflated, to bring the filter **14** into its respective unfurled and furled positions. In practice, as shown by FIGS. **5** to **9**, the device **1** is introduced into said bodily vessel **50** by a percutaneous route and is slid along inside this vessel **50** until each of the series **11**, **12** of blades is placed on one side of the native valve **55** that is to be treated (FIG. **5**). This position is identified using the aforementioned marks. When the device is in this position, the proximal part of the catheter **2** is situated in the heart, preferably in the left ventricle, while the aforementioned distal lateral openings are placed in a peripheral arterial vessel, preferably in the ascending aorta. The balloons **13** and **35** are inflated in such a way as to cause blood to flow only through the passage **15** and prevent blood reflux during the ablation of the valve **55**. A peripheral perfusion system is set in place to facilitate this flow. The blades **30** of the two series **11**, **12** are then deployed (FIG. **6**) by inflating the balloons **31**, then these two series **11**, **12** are moved closer together by sliding the tube **6** with respect to the tube **7**, until the valve **55** is cut through (FIG. **7**). The blades **30** are then returned to their furled position by deflating the balloons **31** while at the same time remaining in their close-together position, which allows the cut-out valve **55** to be held between them. The device **1** is then slid axially in the distal direction so as to bring the bell housing **6***a* to the appropriate position in the vessel **50** (FIG. **8**), after which the valve **10** is deployed by sliding the tube **6** with respect to the tube **5** (FIG. **9**). The balloons **13** and **35** are deflated then the device **1** is withdrawn and the cut-out valve **55** is recovered (FIG. **10**).

FIG. **11** shows a second embodiment of the device **1**, allowing operation on a mitral valve **56**. The same reference numerals are used to denote the same elements or parts as the aforementioned, as long as these elements or parts are identical or similar in both embodiments. In this case, the tubular catheter is replaced by a support wire **2**, on which one of the series of blades is mounted and by a tube engaged over and able to slide along this wire, on which tube the other series of blades is mounted; the passages for inflating the balloons **31** run along this support wire and this tube; the balloon **13** and

the filter **14** are separate from the device **1** and are introduced into the aorta via a peripheral arterial route, by means of a support wire **40** along which the passages for inflating the balloons **13** and **35** run. The device **1**, devoid of balloon **13** and the filter **14**, is for its part introduced into the heart through the peripheral venous system, as far as the right atrium then into the left atrium through the inter-auricular septum, as far as the valve **56**. For the remainder, the device **1** operates in the same way as was mentioned earlier. The invention thus provides a device for replacing a heart valve by a percutaneous route, making it possible to overcome the drawbacks of the prior techniques. Indeed the device **1** is entirely satisfactory as regards the cutting-away of the valve **55**, **56**, making it possible to operate without stopping the heart and making it possible, by virtue of the filter **14**, to prevent any dispersion of valve fragments **55**, **56** into the circulatory system.

The above device may comprise a fourth tube, engaged on and able to slide along the tube **7**, this fourth tube comprising the balloon and the filter mounted on it and allowing said series of blades to be moved in the axial direction independently of said balloon and/or of said filter; the blades may be straight as depicted in the drawing or may be curved toward the axis of the device at their end which has the cutting edge, so as to eliminate any risk of lesion in the wall of the bodily vessel, as shown in FIG. **12**; the filter **14** may be of the self-expanding type and normally kept in the contracted position by a sliding tube, which covers it, making the balloon **35** unnecessary.

FIGS. **13** to **16** represent tubular support **101** for positioning, by percutaneous route, of replacement heart valve **102**. The support structure **101** includes median portion **103**, which contains valve **102**, two extreme wedging portions **104** and wires **105** for connecting these portions **103** and **104**, Median portion **103** also includes peripheral shell **106** provided with anchoring needles **107** and shell **108** made of compressible material. As is particularly apparent from FIG. **13**, each of portions **103** and **104** is formed with an undulating wire, and wires **105** connect pointwise the ends of the undulations of portion **103** to the end of an adjacent wave of portion **104**. Portions **104**, seen in expanded form, have lengths greater than the length of portion **103**, so that when the ends of the wires respectively forming portions **103** and **104** are connected in order to form the tubular support structure **101**, the diameter of portion **103** is smaller than the diameter of portions **104**.

The diameter of portion **103** is such that portion **103** can, as shown by FIG. **17**, support cardiac ring **110** that remains after removal of the deficient native valve, while portions **104** cart support walls **111** bordering ring **110**. These respective diameters are preferably such that said supporting operations take place with slight radial restraint of ring **110** and walls **111**. Portion **103** presents in the deployed state a constant diameter. Portions **104** can have a constant diameter in the form of a truncated cone whose diameter increases away from portion **103**. The entire support structure **101** can be made from a material with shape memory, such as the nickel-titanium alloy known as "Nitinol." This material allows the structure to be contracted radially, as shown in FIG. **16**, at a temperature different form that of the body of the patient and to regain the original shape shown in FIGS. **14** and **15** when its temperature approaches or reaches that of the body of the patient. The entire support structure **101** can also be made from a material that can be expanded using a balloon, such as from medical stainless steel (steel 316 L). Valve **102** can be made of biological or synthetic tissue. It is connected to portion **103** by sutures or by any other appropriate means of attachment. It can also be molded on portion **103**. Shell **106** may be made of "Nitinol." It is connected to the undulations of portion **103** at mid-amplitude, and has needles **107** at the site of its regions connected to these undulations. Needles **107** consist of strands of metallic wire pointed at their free ends, which project radially towards the exterior of shell **106**.

This shell can take on the undulating form which can be seen in FIG. **16** in the contracted state of support **101** and the circular form which can be seen in FIG. **4** in the deployed state of this support **101**. In its undulating form, shell **106** forms undulations **106***a* projecting radially on the outside of support **101**, beyond needles **107**, so that these needles **107**, in the retracted position, do not obstruct the introduction of support **101** in a catheter or, once support **101** has been introduced into the heart using this catheter, do not obstruct the deployment out of this support **1**. The return of shell **6** to its circular form brings needles **107** to a position of deployment, allowing them to be inserted in ring **110** in order to complete the anchoring of support **101**. Shell **108** is attached on shell **106**. Its compressible material allows it to absorb the surface irregularities which might exist at or near ring **110** and thus to ensure complete sealing of valve **102**.

FIG. **18** shows a support structure **101** having a single portion **104** connected to portion **103** by wires **105**. This portion **104** is formed by two undulating wires **114** connected together by wires **115**. FIG. **19** shows a support structure **101** which has portion **103** and portion **104** connected by connecting wires **105**. These portions **103** and **104** have diamond-shaped mesh structures, these mesh parts being juxtaposed in the direction of the circumference of these portions and connected together at the site of two of their opposite angles in the direction of the circumference of these portions **103** and **104**. Wires **105** are connected to these structures at the site of the region of junction of two consecutive mesh parts. These mesh parts also have anchoring hooks **107** extending through them from one of their angles situated in the longitudinal direction of support **101**.

FIG. **20** illustrates, in an enlarged scale, the structure of this portion **104** and of a part of wires **105**, as cut, for example, with a laser from a cylinder of stainless steel, and after bending of sharp ends **107***a* of hooks **107**. These hooks, in a profile view, can have the shape as shown in FIG. **4** or **26**. The structure represented in FIG. **19** also has axial holding portion **120**, which has a structure identical to that of portion **104** but with a coarser mesh size, and three wires **105** of significant length connecting this portion **120** to portion **103**. These wires **105**, on the side of portion **120**, have a single link **105***a* and on the side of portion **103**, a double link **105***b*. Their number corresponds to the three junctions formed by the three valves of valve **102**, which facilitates mounting of valve **102** on support **101** thus formed. The support according to FIG. **19** is intended to be used, as appears in FIG. **21**, when the body passage with the valve to be replaced, in particular the aorta, has a variation in diameter at the approach to the valve. The length of wires **105** connecting portions **103** and **120** is provided so that after implantation, portion **120** is situated in a non-dilated region of said body passage, and this portion **120** is provided so as to engage the wall of the passage.

FIG. **22** shows a structure similar to that of FIG. **19** but unexpanded, except that the three wires **105** have a single wire structure but have an undulating wire **121** ensuring additional support near portion **103**. This wire **121** is designed to support valve **102** with three valve leaflets. FIGS. **23** to **26** show an embodiment variant of the structure of portions **103**, **104** or **120**, when this structure is equipped with hooks **107**. In this case, the structure has a zigzagged form, and each hook **107** has two arms **107***b*; each of these arms **107***b* is connected

to the other arm **107***b* at one end and to an arm of structure **101** at its other end. The region of junction of the two arms **107***b* has bent hooking pin **107***a*.

FIG. **27** shows portion **103** which has two undulating wires **125**, **126** extending in the vicinity of one another and secondary undulating wire **127**. As represented in FIG. **28**, wires **125**, **126** can be used to execute the insertion of valve **102** made of biological material between them and the attachment of this valve **102** to them by means of sutures **127**. FIG. **29** shows a part of support **101** according to FIGS. **13** to **17** and the way in which the compressible material constituting shell **108** can absorb the surface irregularities possibly existing at or near ring **110**, which result from calcifications. FIG. **30** shows support **101** whose shell **106** has no compressible shell. A material can then be applied, by means of an appropriate cannula (not represented), between ring **110** and this shell **106**, this material being able to solidify after a predetermined delay following application.

FIG. **31** shows support **101** whose shell **106** has a cross section in the form of a broken line, delimiting, on the exterior radial side, a lower shoulder. Housed in the step formed by this shoulder and the adjacent circumferential wall is peripheral shell **108** which can be inflated by means of a catheter (not represented). This shell **108** delimits a chamber and has a radially expandable structure, such that it has in cross section, in the inflated state, two widened ends projecting on both sides of shell **106**. This chamber can receive an inflating fluid that can solidify in a predetermined delay following its introduction into said chamber. Once this material has solidified, the inflating catheter is cut off.

FIGS. **32** and **33** show support **101** whose shell **106** receives inflatable insert **108** which has a spool-shaped cross section in the inflated state; this insert **108** can be inflated by means of catheter **129**. Insert **108** is positioned in the uninflated state (FIG. **32**) at the sites in which a space exists between shell **106** and existing cardiac ring **110**. Its spool shape allows this insert (cf. FIG. **33**) to conform as much as possible to the adjacent irregular structures and to ensure a better seal.

FIG. **34** shows balloon **130** making it possible to deploy support **101** according to FIGS. **19** to **21**. This balloon **130** has cylindrical portion **131** whose diameter in the inflated state makes possible the expansion of holding portion **120**, a cylindrical portion **132** of lesser diameter, suitable for producing the expansion of portion **103**, and portion **133** in the form of a truncated cone, makes possible the expansion of portion **104**. As shown by FIG. **35**, portion **132** can be limited to what is strictly necessary for deploying portion **103**, which makes it possible to produce balloon **130** in two parts instead of a single part, thus limiting the volume of this balloon **130**.

FIG. **36** shows support **101** whose median portion **103** is in two parts **103***a*, **103***b*. Part **103***a* is made of undulating wire with large-amplitude undulations, in order to support valve **102**, and part **103***b*, adjacent to said part **103***a* and connected to it by bridges **135**, is made of undulating wire with small-amplitude undulations. Due to its structure, this part **103***b* presents a relatively high radial force of expansion and is intended to be placed opposite ring **110** in order to push back: the native valve sheets which are naturally calcified, thickened and indurated, or the residues of the valve sheets after valve resection against or into the wall of the passage. This axial portion **103***a*, **103***b* thus eliminates the problem induced by these sheets or residual sheets at the time of positioning of valve **102**.

It is apparent from the preceding that one embodiment of the invention provides a tubular support for positioning, by percutaneous route, of a replacement heart valve, which provides, due to its portions **103** and **104**, complete certitude as to its maintenance of position after implantation. This support also makes possible a complete sealing of the replacement valve, even in case of a cardiac ring with a surface that is to varying degrees irregular and/or calcified, and its position can be adapted and/or corrected as necessary at the time of implantation.

Referring to FIGS. **37** and **38**, the present invention also comprises an alternative prosthetic valve assembly **310**, which further comprises a prosthetic valve **312**, a valve support band **314**, distal anchor **316**, and a proximal anchor **318**. Valve **312** can be made from a biological material, such as one originating from an animal or human, or from a synthetic material, such as a polymer. Depending upon the native valve to be replaced, the prosthetic valve **312** comprises an annulus **322**, a plurality of leaflets **324**, and a plurality of commissure points **326**. The leaflets **324** permit the flow of blood through the valve **312** in only one direction. In the preferred embodiment, the valve annulus **322** and the commissure points **326** are all entirely supported within the central support band **314**. Valve **312** is attached to the valve support band **314** with a plurality of sutures **328**, which can be a biologically compatible thread. The valve could also be supported on band **314** with adhesive, such as cyanoacrylate.

In one embodiment, valve **312** can be attached to, or may integral with, a sleeve or sheath (not shown). The sheath is secured to the valve support band **314** such that the outer surface of the sheath is substantially in contact with the inner surface of the valve support band **314**. In such embodiment, the sheath can be attached to the valve support band **314** with sutures **328**. FIG. **40** is a photograph of the concept of this alternative embodiment. If desired, the sheath can be secured to the outside of valve support band **314** (not shown).

Referring to FIGS. **37** and **38**, in one embodiment, valve support band **314** is made from a single wire **342** configured in a zigzag manner to form a cylinder. Alternatively, valve support band **314** can be made from a plurality of wires **342** attached to one another. In either case, the band may comprise one or more tiers, each of which may comprise one or more wires arranged in a zigzag manner, for structural stability or manufacturing ease, or as anatomical constraints may dictate. If desired, even where the central valve support **314** is manufactured having more than one tier, the entire valve support **314** may comprise a single wire. Wire **342** can be made from, for example, stainless steel, silver, tantalum, gold, titanium, or any suitable plastic material. Valve support band **314** may comprise a plurality of loops **344** at opposing ends to permit attachment to valve support band **314** of anchors **316** and/or **318** with a link. Loops **344** can be formed by twisting or bending the wire **342** into a circular shape. Alternatively, valve support band **314** and loops **344** can be formed from a single wire **342** bent in a zigzag manner, and twisted or bent into a circular shape at each bend. The links can be made from, for example, stainless steel, silver, tantalum, gold, titanium, any suitable plastic material, solder, thread, or suture. The ends of wire **342** can be joined together by any suitable method, including welding, gluing or crimping.

Still referring to FIGS. **37** and **38**, in one embodiment, distal anchor **316** and proximal anchor **318** each comprise a discrete expandable band made from one or more wires **342** bent in a zigzag manner similar to the central band. Distal anchor band **316** and proximal anchor band **318** may comprise a plurality of loops **344** located at an end of wire **342** so that distal anchor band **316** and proximal anchor band **318** can each be attached to valve support band **314** with a link. Loop **344** can be formed by twisting or bending the wire **342** into a circular shape. As desired, distal and/or proximal anchors

316, 318 may comprise one or more tiers, as explained before with the valve support 314. Likewise, each anchor may comprise one or more wires, regardless of the number of tiers. As explained above in regard to other embodiments, the distal anchor may be attached to the central valve support band 314 directly, as in FIG. 37, or spaced distally from the distal end of the valve support 314, as shown above schematically in FIGS. 18, 19, 21 and 22. In the later instance, one or more struts may be used to link the distal anchor band to the valve support band, as described above.

Distal anchor band 316 has a first end 350 attached to the central valve band 314, and a second end 352. Similarly, proximal anchor band 318 has first attached end 354 and a second end 356. The unattached ends 352, 356 of the anchors 316, 318, respectively are free to expand in a flared manner to conform to the local anatomy. In such embodiment the distal and proximal anchor bands 316, 318 are configured to exert sufficient radial force against the inside wall of a vessel in which it can be inserted. Applying such radial forces provides mechanical fixation of the prosthetic valve assembly 310, reducing migration of the prosthetic valve assembly 310 once deployed. It is contemplated, however, that the radial forces exerted by the valve support 314 may be sufficient to resist more than a minimal amount of migration, thus avoiding the need for any type of anchor.

In an alternative embodiment, distal and proximal anchors may comprise a fixation device, including barbs, hooks, or pins (not shown). Such devices may alternatively or in addition be placed on the valve support 314. If so desired, the prosthetic valve assembly 310 may comprise an adhesive on the exterior thereof to adhere to the internal anatomical lumen.

Prosthetic valve assembly 310 is compressible about its center axis such that its diameter may be decreased from an expanded position to a compressed position. When placed into the compressed position, valve assembly 310 may be loaded onto a catheter and transluminally delivered to a desired location within a body, such as a blood vessel, or a defective, native heart valve. Once properly positioned within the body the valve assembly 310 can be deployed from the compressed position to the expanded position. FIG. 39 is a photograph of one embodiment of the prosthetic valve assembly described with both distal and proximal anchor bands while FIG. 49 is a photograph showing only a distal anchor.

In the preferred embodiment, the prosthetic valve assembly 310 is made of self-expanding material, such as Nitinol. In an alternative embodiment, the valve assembly 310 requires active expansion to deploy it into place. Active expansion may be provided by an expansion device such as a balloon.

As referred to above in association with other embodiments, the prosthetic valve assembly of the present invention is intended to be percutaneously inserted and deployed using a catheter assembly. Referring to FIG. 41A, the catheter assembly 510 comprises an outer sheath 512, an elongate pusher tube 514, and a central tube 518, each of which are concentrically aligned and permit relative movement with respect to each other. At a distal end of the pusher tube 514 is a pusher tip 520 and one or more deployment hooks 522 for retaining the prosthesis assembly (not shown). The pusher tip 520 is sufficiently large so that a contracted prosthesis assembly engages the pusher tip 520 in a frictional fit arrangement. Advancement of the pusher tube 514 (within the outer sheath 512) in a distal direction serves to advance the prosthesis relative to the outer sheath 512 for deployment purposes.

At a distal end of the central tube 518 is an atraumatic tip 524 for facilitating the advancement of the catheter assembly 510 through the patient's skin and vasculature. The central tube 518 comprises a central lumen (shown in phantom) that can accommodate a guide wire 528. In one embodiment, the central lumen is sufficiently large to accommodate a guide wire 528 that is 0.038 inch in diameter. The guide wire can slide through the total length of the catheter form tip to handle ('over the wire' catheter) or the outer sheath 512 can be conformed so as to allow for the guide wire to leave the catheter before reaching its proximal end ('rapid exchange' catheter). The space between the pusher tube 514 and the outer sheath 512 forms a space within which a prosthetic valve assembly may be mounted.

Hooks 522 on the distal end of the pusher tube 514 may be configured in any desired arrangement, depending upon the specific features of the prosthetic assembly. With regard to the prosthesis assembly of FIGS. 37 and 38, the hooks 522 preferably comprise an L-shaped arrangement to retain the prosthesis assembly axially, but not radially. With a self-expanding assembly, as the prosthesis assembly is advanced distally beyond the distal end of the outer sheath 512, the exposed portions of the prosthesis assembly expand while the hooks 522 still retain the portion of the prosthesis still housed within the outer sheath. When the entire prosthesis assembly is advanced beyond the distal end of the outer sheath, the entire prosthesis assembly is permitted to expand, releasing the assembly from the hooks. FIGS. 42 through 45 show the distal end of one embodiment of the catheter assembly, three of which show sequenced deployment of a valve prosthesis.

In an alternative embodiment of the valve prosthesis, loop elements extend axially from one end of the prosthesis, where the loop elements can be retained by the hooks 522 during deployment. This alternative embodiment is shown in the photograph of FIG. 48, where the photographs of FIGS. 46 and 47 show a catheter assembly used for deploying the alternative prosthesis assembly. By adding loop elements to the prosthesis, the prosthesis may be positioned with its support and anchors fully expanded in place while permitting axial adjustment into final placement before releasing the prosthesis entirely from the catheter.

FIG. 41B shows the proximal end of the catheter assembly 510, which to a greater extent has many conventional features. At the distal end of the pusher tube 514 is a plunger 530 for advancing and retreating the pusher tube 514 as deployment of the prosthesis assembly is desired. As desired, valves and flush ports proximal and distal to the valve prosthesis may be provided to permit effective and safe utilization of the catheter assembly 510 to deploy a prosthesis assembly.

In one embodiment, prosthetic valve assembly 310 (not shown) is mounted onto catheter 510 so that the valve assembly 310 may be delivered to a desired location inside of a body. In such embodiment, prosthetic valve assembly 310 is placed around pusher tip 520 and compressed radially around the tip 520. The distal end of prosthetic valve assembly 310 is positioned on the hooks 522. While in the compressed position, outer sheath 512 is slid toward the atraumatic tip 524 until it substantially covers prosthetic valve assembly 310.

To deliver prosthetic valve assembly 310 to a desired location within the body, a guide wire 528 is inserted into a suitable lumen of the body, such as the femoral artery or vein to the right atrium, then to the left atrium through a transseptal approach, and maneuvered, utilizing conventional techniques, until the distal end of the guide wire 528 reaches the desired location. The catheter assembly 510 is inserted into the body over the guide wire 528 to the desired position. Atraumatic tip 524 facilitates advancement of the catheter assembly 510 into the body. Once the desired location is reached, the outer sheath 512 is retracted permitting the valve prosthesis to be released from within the outer sheath 512,

and expand to conform to the anatomy. In this partially released state, the position of prosthetic valve **310** may be axially adjusted by moving catheter assembly **510** in the proximal or distal direction.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, and not restrictive and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A prosthetic valve assembly for use in replacing a deficient native valve, the valve assembly comprising:

a valve having a plurality of leaflets, a base, and a plurality of commissure points;

a valve support comprising a generally cylindrical band comprising a plurality of expandable cells, the valve support configured to be collapsible for transluminal delivery and expandable to contact the anatomical annulus of the native valve when the assembly is positioned in situ, said generally cylindrical band of the valve support supporting the base and the commissure points of the valve; and

an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment:

wherein the anchor comprises one or more hooks extending radially outward from the valve support.

2. The valve assembly of claim **1**, wherein the valve support comprises nickel titanium.

3. A method of replacing a deficient native valve comprising the steps of:

providing a prosthetic valve assembly, the assembly comprising a valve, a valve support comprising a plurality of expandable cells and having the base and the commissures of the valve positioned and secured at or adjacent the expandable cells, the valve support further comprising an anchor;

collapsing the valve support and anchor to fit on a distal portion of a catheter;

advancing the catheter to the deficient native valve to a position within adjacent the leaflets and within the annulus of the deficient native valve;

deploying the valve assembly within the deficient native valve, whereby the valve support expands against the leaflets of the deficient native valve; and

withdrawing the catheter, leaving the valve assembly to function in place of the deficient native valve.

4. The method of claim **3**, further comprising the step of positioning the valve support and anchor within a generally tubular sheath extending around the distal portion of the catheter.

5. The method of claim **3**, wherein the anchor is self-expanding.

6. The method of claim **3**, wherein the valve support is self-expanding.

7. The method of claim **3**, wherein the valve support is balloon-expandable.

8. The method of claim **3**, further comprising the step of securing a portion of the valve support to the catheter.

9. The method of claim **3**, wherein deploying the valve assembly comprises the step of crushing the native valve leaflets against the native valve annulus.

10. The method of claim **3**, wherein the prosthetic valve assembly further comprises an anchor for engaging a lumen wall for preventing substantial migration of the valve assembly when positioned in place.

11. The method of claim **10**, wherein the anchor is spaced from the valve support.

12. A prosthetic valve assembly for use in replacing a deficient native valve, the valve assembly comprising:

a valve having a base, a plurality of leaflets and commissure points;

a valve support comprising a plurality of expandable cells and a plurality of longitudinal bars, the valve support configured to be collapsible for transluminal delivery and expandable to contact the anatomical annulus of the native valve when the assembly is positioned in situ, said valve support supporting the base, wherein the commissure points of the valve are secured at the longitudinal bars and adjacent one or more of the expandable cells, and wherein the longitudinal bars of the valve support further comprise a plurality of holes, wherein the plurality of leaflets are secured to the longitudinal bars via suture lines passing through the plurality of holes.

13. The valve assembly of claim **12**, wherein the valve support is self-expanding.

14. The valve assembly of claim **12**, wherein the valve support is balloon expandable.

15. The valve assembly of claim **12**, wherein the valve support is configured to press radially against the native valve leaflets to hold the native valve leaflets against walls of the native valve annulus and/or against walls of an adjacent lumen to thereby prevent the native valve leaflets from obstructing the native valve annulus.

* * * * *

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge James V. Selna and the assigned discovery Magistrate Judge is Marc Goldman.

The case number on all documents filed with the Court should read as follows:

SACV11- 961 JVS (MLGx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

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NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[ ] **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

[X] **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

[ ] **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

CENTRAL DISTRICT OF CALIFORNIA

Medtronic CoreValve LLC, Medtronic CV Luxembourg S.A.R.L., and Medtronic Vascular Galway Ltd.

Plaintiff

v.

Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.), Inc.

Defendant

Civil Action No. SACV11-00961 JVS (MLGx)

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Edwards Lifesciences Corporation, Edwards Lifesciences LLC,
Edwards Lifesciences (U.S.) Inc.
One Edwards Way
Irvine, CA 92614

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

David Martinez, Esq.
Robins, Kaplan, Miller & Ciresi L.L.P.
2049 Century Park East, Suite 3400,
Los Angeles, CA 90067-3208

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: JUN 27 2011

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____ _____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)
MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L. AND MEDTRONIC VASCULAR GALWAY LTD

DEFENDANTS
EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, AND EDWARDS LIFESCIENCES (U.S.) INC.

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)
David Martinez (310) 552-0130
ROBINS, KAPLAN, MILLER & CIRESI L.L.P.
2049 Century Park East, Suite 3400, Los Angeles, CA 90067-3208

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1 U.S. Government Plaintiff ☑ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☑ Yes ☐ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☐ Yes ☑ No ☐ **MONEY DEMANDED IN COMPLAINT: $** _____

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
Action for patent infringement (Violation of 35 U.S.C. § 271)

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 480 Consumer Credit
☐ 490 Cable/Sat TV
☐ 810 Selective Service
☐ 850 Securities/Commodities/ Exchange
☐ 875 Customer Challenge 12 USC 3410
☐ 890 Other Statutory Actions
☐ 891 Agricultural Act
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Info. Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes

CONTRACT
☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
☐ 153 Recovery of Overpayment of Veteran's Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability
☐ 196 Franchise

REAL PROPERTY
☐ 210 Land Condemnation
☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property

TORTS PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Fed. Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
☐ 362 Personal Injury-Med Malpractice
☐ 365 Personal Injury-Product Liability
☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
☐ 462 Naturalization Application
☐ 463 Habeas Corpus-Alien Detainee
☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

BANKRUPTCY
☐ 422 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/Accommodations
☐ 444 Welfare
☐ 445 American with Disabilities - Employment
☐ 446 American with Disabilities - Other
☐ 440 Other Civil Rights

PRISONER PETITIONS
☐ 510 Motions to Vacate Sentence Habeas Corpus
☐ 530 General
☐ 535 Death Penalty
☐ 540 Mandamus/ Other
☐ 550 Civil Rights
☐ 555 Prison Condition

FORFEITURE / PENALTY
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R. & Truck
☐ 650 Airline Regs
☐ 660 Occupational Safety /Health
☐ 690 Other

LABOR
☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
☐ 791 Empl. Ret. Inc. Security Act

PROPERTY RIGHTS
☐ 820 Copyrights
☑ 830 Patent
☐ 840 Trademark

SOCIAL SECURITY
☐ 861 HIA (1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW (405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: SACV11-00961

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☑ No ☐ Yes
If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☑ No ☐ Yes
If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:
(Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Medtronic Corevalve LLC: Orange County	Medtronic CV Luxembourg S.a.r.l.: Luxembourg Medtronic Vascular Galway Ltd.: Galway, Ireland

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc.: Orange County	

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange County	

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**
Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): _____ Date June 24, 2011
David Martinez

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))